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AIDS EDUCATION, CARE, AND DRUG DEVELOPMENT

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

EXAMINING THE ADEQUACY OF THE FEDERAL GOVERNMENT EFFORTS TO COMBAT AIDS, WITH REGARD TO EDUCATION, CARE, AND DRUG DEVELOPMENT

FEBRUARY 7, 1989

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AIDS EDUCATION, CARE, AND DRUG DEVELOPMENT

TUESDAY, FEBRUARY 7, 1989

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 10:35 a.m., in Room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Pell, Simon, Adams, Mikulski, Hatch, Jeffords, and Durenberger.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

We have called this hearing as a sign of the high priority our committee intends to give the AIDS crisis and the HIV epidemic in the new Congress. As long as the AIDS death toll mounts, and the suffering spreads, Congress must continue to reassess the adequacy of our national response to this public health catastrophe.

Undeniably, the AIDS virus has unleashed untold pain and suffering. However, it also presents our society with a fundamental challenge—to do all within our power to prevent more people from becoming infected with the virus.

One of our purposes this morning is to assess the progress that is being made or that needs to be made in our AIDS education efforts. Mere public awareness of the AIDS problem is not enough. The real goal must be a fundamental change in the attitudes and personal behavior of millions of individuals within our society.

This morning we also look forward to receiving information on the Federal Government's programs in the areas of patient care and AIDS treatments. We will hear from the Institute of Medicine, which has sent updated recommendations to President Bush as part of its ongoing process of confronting AIDS. The information we receive here this morning marks the continuation of the committee's oversight process on AIDS that is a central part of our work.

We welcome this morning representatives from various agencies working on AIDS. We are mindful that top health appointees in the new administration have not yet been confirmed in their positions. Equally important, the Congress has yet to receive the new President's proposed budget amendments, including the level of funding for the comprehensive AIDS legislation enacted at the close of the 100th Congress. That legislation, which I am pleased to

have cosponsored with the distinguished ranking minority member of this committee, provides a bipartisan framework for our efforts, and I look forward to working closely with the new Administration to achieve our goals.

In passing that comprehensive legislation, Congress sought a coordinated and compassionate response to this health emergency—including accelerated research, expanded education and prevention, and more humane and cost-effective care for those with AIDS.

We are here this morning to begin reviewing the steps needed to implement that bipartisan agenda. Unquestionably, many of the most difficult decisions about AIDS lie ahead. Before this epidemic can be brought under control, it is essential to remedy the problem of discrimination against those infected with the virus. It is my hope that all members of this committee will cosponsor and support passage of the Americans With Disabilities Act in order to halt discrimination against any individual with a disability, including infection with the AIDS virus.

In his campaign, President Bush pledged his support for this approach, and I am hopeful that the President and the Administration will join us in making clear that discrimination against people with AIDS is unacceptable. We need to harness the creativity and the resources necessary to meet this challenge head-on. Working together, the new Congress and the new administration can provide fresh leadership on AIDS and implement a Federal policy based on compassion and the best recommendations of the Nation's public health experts.

It is clear that much remains to be done. The virus that has already wrecked havoc in America's gay community is now accelerating its course through our inner cities. Prompt and decisive action is needed to prevent the further spread of the epidemic into the black and Hispanic communities.

I will place the rest of my statement in the record and recognize the Senator from Utah.

REMAINDER OF SENATOR KENNEDY'S OPENING STATEMENT

Last year's bill authorized up to $30 million to support the efforts of minority organizations working to combat the AIDS virus and an additional $25 million to reach underserved populations. It also authorized $45 million of paid advertising to communicate AIDS prevention information. Such messages can bring life saving information to our inner cities. Many communities are already reeling from the burdens of providing hospital services for people with AIDS and HIV-related illness. As part of this morning's agenda, we will hear about steps being taken to provide cost-effective alternatives such as federal funding for AIDS home and community-based care.

While we hope that both President Bush and the Budget Committees can find the resources to fund this AIDS home care initiative, it is by no means a long term solution to the AIDS health care services dilemma.

The AIDS epidemic continues to expose the shortcomings and inequities of our nation's system of health care delivery. There is, for instance, no long term plan for helping people with this devastat-

ing illness obtain the drugs that may be their only hope of survival.

All the while, more and more people with absolutely no health insurance and no savings will be counted among tomorrow's AIDS cases. Who pays for their care? Will our society stand by as the epidemic of AIDS migrates onto the sidewalks and merges with the epidemic of homelessness? No, I believe that Americans are prepared to do what is necessary to meet this emergency head on. And, I believe they expect no less from their government.

Finally, this morning, we will also inquire what has been done to expedite desperately needed medical answers to AIDS. Specifically, we will focus on the drug review and approval procedures of the Food and Drug Administration. Last July in this committee, we heard about the revamping of FDA procedures to make treatments for life-threatening disease more rapidly and readily available. Just this morning, for example, an AIDS drug that prevents AIDS related pneumonia is being officially released under the FDA's new rules, and I am hopeful that these new procedures can be used to expedite the approval of other drugs now in the pipeline.

In many other ways, we have new opportunities to work together to stop the untold human suffering caused by AIDS. Now is the time to give this epidemic the higher priority it deserves.

Senator Hatch.

OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. Thank you, Mr. Chairman.

Mr. Chairman, one of our major last health accomplishments together was to see the Health Omnibus Bill signed into law. This legislation had as its centerpiece the expansion of Federal/State efforts to battle AIDS. This law was, in many ways a masterpiece of bipartisanship, and its formation was driven by discussion, cooperation and consensus.

Now, Mr. Chairman, today's hearing was to build upon this consensus and to highlight important parts of that legislation. Unfortunately, such cooperation was absent in the scheduling and selecting of witnesses for this hearing. I am sure that this was just an oversight, but nevertheless, as the ranking Republican member, I have to protect the rights of the minority members as established under the Standing Rules of the Senate at the outset of the 101st Congress.

Such rules require seven days' notice prior to a hearing—we have never been sticklers on that—but the notice of the hearing was dated February 1 and received by my office on February 2. Because of the last-minute scheduling of this hearing, the minority did not have the opportunity to invite any witnesses. Therefore, I am requesting a minority day of hearings, and I have a letter that, of course, I have given to you, signed by all seven Republicans on the committee, which I hope you will give great consideration to.

We are all in agreement that we have to strive to work in a bipartisan manner to fight this tragic disease of AIDS. At the same time, however, it seems to me we have to protect the rights of those who are in the minority.

We have appreciated the opportunity for consultation that you, in particular, Mr. Chairman, have generally accorded to us in the past, which I think always has reflected the spirit of bipartisanship as well as the adherence to the letter of the law regarding committee procedures.

So it is certainly my hope, Mr. Chairman, that we can continue in this vein, and I look forward to doing it, because I enjoy working with you, and I enjoy doing the things that we have been able to do in the past where we have agreed. And certainly, there are pressing national issues which demand that we work together.

Now, Mr. Chairman, there is no other compelling public health issue threatening America more than the disease of AIDS. We made some significant progress during the last Congress, but more needs to be done, and it is time to review the laws which thwart the expeditious approval of various drugs for AIDS victims who are facing death. It is indeed time to fund compassionate, cost-effective home health care programs to treat victims with AIDS. And it is indeed time to reach out to all Americans with a clear and accurate educational message that AIDS kills and that the only way to stop the spread of this disease is to eliminate risky behavior.

The main focus of this hearing is to highlight the need for resources for the Public Health Service. Commissioner Young, I have experienced first-hand the resource needs of the Food and Drug Administration during my tours of FDA. You have done a heroic job of balancing the rigid requirements of the Food, Drug and Cosmetic Act with the need to be sensitive to those who are dying from AIDS. You have shown great wisdom in finding this balance while managing the entire Food and Drug Administration, so I really look forward to your testimony.

Dr. Sam Matheny, I am also aware of the promising work undertaken by the Health Resources and Services Administration under your and Dr. Sundwall's leadership to develop compassionate, caring demonstration programs to treat those with AIDS. There must be more that we can do to put these programs in place around the country.

And, Dr. Gary Noble, I want to commend you and Dr. Mason for spearheading the Centers for Disease Control's programs to educate Americans on the risk of spreading AIDS. I look forward to all of your views on sharing these duties with local and State health officials.

As long as we work together toward a national AIDS policy based on consensus and compassion, rather than criticism and conflict, we are going to reduce fear and anxiety among all Americans. Instead, we can spread knowledge and understanding about AIDS as well as the hope that it can be conquered.

In that regard I want to congratulate our chairman for the work that he has done on this subject in the past and just tell him that I respect that, I respect him, and I look forward to working with him as we start this 101st Congress with regard to this particular issue.

I think if we can get together—and I believe we can—we can go a long way toward resolving some of these very serious problems that have beset America and, frankly, the whole world.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

I will put in the record the notice that, as I understand, was provided by your staff, that indicates February 1st and then the received date of February 2. I will also put in the record a committee notice which was targeted, sent January 31, 1989, signed by Deborah Sutinen, which has notice about this particular hearing.

[The committee correspondence referred to follows:]

February 1, 1989

Committee on Labor and Human Resources
Tentative Meeting Schedule

Thursday, Feb. 2 10:00 a.m.	SD-430	Subc. on Children, Family, Drugs and Alcoholism Hearing "Family and Medical Leave Act"
Tuesday, Feb. 7 10:00 a.m.	SD-430	Full Committee Hearing, "AIDS Education, Care & Drug Development Oversight, I"
Wednesday, Feb. 8 10:00 a.m.	SD-430	Full Committee Executive Session to consider S.4, "Minimum Wage" and to adopt committee rules

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United States Senate
COMMITTEE ON LABOR AND
HUMAN RESOURCES
WASHINGTON, DC 20510-6300

COMMITTEE NOTICE

To : All Committee Members

Subject: Hearing on "AIDS Education, Care and Drug Development Oversight, Part I"

Date : Tuesday, February 7, 1989

Time : 10:00 a.m.

Place : SD-430 Dirksen Building

Deborah Sutinen
Staff Assistant

1/31/89

The CHAIRMAN. The important point is, we are glad to work with the minority. It is difficult for me to believe, quite frankly, that calling administration witnesses, all of whom have been a part of or appointed by the administration, or are career individuals, is a partisan endeavor——

Senator HATCH. And we are glad to have them.

The CHAIRMAN [continuing]. And, since we are hearing from Frank Young, who was appointed by the administration, and representatives of Health Resources and Services Administration, and then from Centers for Disease Control and the Institute of Medicine, I frankly do not see your concern.

But as always, we were glad to afford the opportunity, if there were special individuals that the Minority wanted whom they thought would be informative to the particular subject matter. The essential mandate of the legislation which you so effectively cosponsored was to instruct these particular agencies to take certain action. And that is why we invited the representatives of those agencies here today; to see if they have complied with the law that we passed. It was not a general hearing on AIDS, but it was designed for the oversight of the legislation that you so effectively helped steer through the Senate.

I want to make it very clear that we recognize that there are various personnel positions within the Administration that are yet to be filled. But this hearing is targeted as an oversight hearing on the specific legislation that was passed last year. As part of that process we will look at the need for expansion of personnel in the CDC, where we are moving in the development of a home care program for people with AIDS, and followup on the hearings that we held with Dr. Young last year on expediting the approval process for AIDS drugs.

So I appreciate what the Senator has stated in terms of having a balanced hearing. We always hope to; perhaps we do not do everything the minority wants, including accommodating every witness, but certainly in the general scope of any subject matter, we are willing to include representatives of the minority. If the minority believes in our oversight function, where this committee and the legislation were quite specific in terms of the instructions, that we omitted a particular area of concern, we are more than willing to hear any recommendations from the minority to address those particular needs.

We have worked closely together and hope that we will continue to do so. We certainly want to send a very clear message of the seriousness with which we look at this issue. That is basically why we are here.

Senator HATCH. Mr. Chairman, if I could just respond.

The CHAIRMAN. Sure.

Senator HATCH. We have no objection to the witnesses that you have. They are absolutely crucial and critical to this subject. I think what I am raising here is that we have found at times in the past that sometimes we are not given enough time, or we are not even consulted with regard to witnesses by staff. What I want to do is to just make sure that we do that in the future. I have no gripes about you. You and I have worked well in these areas, but we just want to make sure we can continue to do it in the future. And you

know, every once in a while, the minority might have somebody they would like to hear from in addition to the administration witnesses.

The CHAIRMAN. That is fine.

Do any of my colleagues feel compelled to make a comment?

Yes, Senator Durenberger.

Senator DURENBERGER. Mr. Chairman, I just want to ask unanimous consent to put in a statement.

The CHAIRMAN. Fine.

Senator DURENBERGER. The only thing I would say on behalf of my colleague, the leader on this side, is that as a new member of the committee, it sort of feels like getting on one of these treadmills, where they have got the speed turned on faster than your capacity to run; and to see this committee hitting the ground, running, and here is minimum wage, and here is AIDS—it is sort of like: Where have I been?

The CHAIRMAN. Yes, well, that is the joy of serving on this committee.

Senator DURENBERGER. Yes, that is great. But if there is a sense maybe that Orrin is reflecting, it is that he may be used to that, but some of the rest of us may need a little more time. But I must say that it is wonderful to join a committee that really is up-to-speed.

Senator HATCH. Senator, you had better get used to it on this committee. It doesn't get better, it gets worse. [Laughter.]

The CHAIRMAN. Further comments?

[The prepared statement of Senator Durenberger follows:]

Statement By Senator Dave Durenberger
Senate Labor Committee Hearing on AIDS
February 7, 1989

Mr. Chairman, the rapid spread of the acquired immunodeficiency syndrome (AIDS) has been one of the most remarkable - and deadly - developments in the field of infectious deseases during this century. It is projected that there are close to a million and a half people in the United States infected with the AIDS virus, and the projections getting worse every day. Already the ninth leading cause of death in this country, it is estimated that before 1991 AIDS will overtake automobile accidents as the single largest cause of death for individuals ages 20-49.

While there is still no cure to this fatal disease, we are gaining a greater understanding of this disease everyday. As a public health emergency of pandemic proportions, the federal government has a responsibility to fund education, confidential testing, and research. We need to educate and counsel the public on the seriousness of the emergency and the need to put and end to the behavior which is associated with the spread of AIDS. It is important that AIDs education programs include not only a discemination of information, but are also aimed at preventive methods designed to affect the attitude and behavior of individuals. Knowledge about the disease is not enough, we need to act on that knowledge.

We need to protect an individual's right to privacy. We do not want to drive this problem underground by not protecting the confidentiality of the testing. We must attact the disease, not the victim. We must ensure that no individual is discriminated against because he or she has AIDS.

Another pressing issue that must be addressed at the federal level is the pressure of expediting the approval of AIDS-related drugs. The FDA is facing the increasing demand for the expediting of drugs. We must be able to strike a balance between the streamlining the approval of drugs and the continued essurance of public safety.

America faces a disease that is fatal and spreading. It calls for urgency, not panic. It calls for compassion, not blame. It calls for understanding, not ignorance. It's also important that America not reject those who have the disease, but care for them with dignity and kindness. This is a battle against disease, not our fellow Americans.

The CHAIRMAN. Dr. Young, we look forward to your testimony. We will include it all in the record, and please proceed in whatever way you wish.

STATEMENT OF DR. FRANK YOUNG, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD, ACCOMPANIED E DR. PAUL PARKMAN, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FDA, AND DR. JAMES M. BILSTEAD, DIRECTOR, OFFICE OF DRUG EVALUATION, II, CENTER FOR DRUG EVALUATION AND RESEARCH, FDA

Dr. YOUNG. Thank you, Mr. Chairman.

I am particularly pleased to have the opportunity to be here today. Since the testimony is comprehensive, I would like to make some points. I would also like to illustrate these points with the charts that I have on the side, if that meets with your approval.

First, I would like to state very clearly that AIDS is the highest priority of the Food and Drug Administration. We see no greater challenge facing the FDA and, in fact, facing the Public Health Service and the Nation than dealing with this very difficult disease.

During the period of time since we spoke last with this committee in mid-1988, a number of things have been put into place. I would like to demonstrate this with the charts that I have and show you the progress that has occurred in that period of time, if I may, sir.

When we were here in July, it was not possible to go into detail about what we had been working on in regard to changing the process. But this fundamentally is the modification that was made in response to the request of then Vice President Bush in the Regulatory Reform Committee and which was endorsed by both Governor Dukakis and Vice President Bush in the first debate.

There is a substantive change in the way FDA is developing its processes. As the chairman and I spoke at the last committee meeting, we felt very strongly that it was important for FDA to get involved early in the process and even in the animal studies. And since that time, Mr. Chairman, I have met with a number of individual sponsors and looked at ways in which we could reduce the number of animal studies and speed the process through to the IND.

The most important modification in this chart is the willingness by the FDA to work very carefully with sponsors to try to frame the questions. In this fashion, we feel that it is imperative to get good Phase I studies, focusing on safety issues, and then to meet with the sponsor at the end of Phase I, framing the efficacy study, if at all possible, for Phase II.

If this can be done, we hope that at the end of Phase II that there will be sufficient information to develop a treatment IND—if there is sufficient information—that would be in place during the time the new drug application is being reviewed and even during the time that it is being prepared by the sponsor. If there are insufficient data, one would then go into a Phase III study. In this fashion, one can decrease by approximately 50 percent the total time for the development of drugs.

I must emphasize that this is not a shortcut in safety and effectiveness. The attempt is to design with the sponsor the circle of uncertainty and try to hit that bull's-eye rather than to have random trials occurring and then find that at a later date those trials are inadequate for a decision. The concept is to get it right the first time.

We have had successes, and there are two drugs—one that has gone completely through this approval process—the drug. The NDA was submitted in October, and the drug was approved January 25—one of the fastest approval times within FDA since the last submission of data.

You have seen recently the publicity on the treatment IND for aerosolized pentamidine, which I will return to, in which the study was on approximately 408 people.

So that there is a movement in this area.

The second point that I would like to make is that there has been a marked increase in the number of new investigations of drug applications as a function of time. Right now, we have 70 immunomodulators before the agency as investigational new drug applications. This has increased from the approximately 50—and I have those that I will submit for the record—that we had in July when we were here.

There are 49 diagnostics, 43 antivirals, and 41 opportunistic infection drugs that are under some form of clinical study. By this, I mean that an IND has been filed, and these are somewhere in the process. Our commitment to the American people is as soon as we see evidence that there may be effectiveness and evidence that the drug is safe, we will either respond to a treatment IND request by the sponsor or in fact call the sponsor in. That is what we did essentially with aerosolized pentamidine. On the Wednesday before Christmas, we reviewed the data, called the company immediately after; the company came in on Thursday; by Friday morning, they decided to go with a treatment IND; and by Friday noon, we called the National Institute of Allergy and Infectious Diseases to enlist their help, because this was a trial sponsored not through NIAID, but the first sponsored through a community research initiative—a program that this committee has been very interested in.

That trial did not require a placebo control. I will return to the clinical endpoints in a few moments.

This increase has been profound. If one looks at the upward swing, starting with 1981, where there were no new investigational drugs, we have had essentially a doubling every year of the drugs that have been submitted to the agency. This creates an enormous problem for the agency, because we need to have reviewers who are trained, and it takes between 1 and 2 years to train a reviewer to meet this challenge.

You had asked, Mr. Chairman, where our resources have been deployed, and you can see that in this chart. Starting in 1984, one of the marked increases that we have is in the field of biologics. The biologics include diagnostics, immunomodulators, vaccines, and many of the drugs of biotechnology.

The drug branch, which reviews the antivirals and the opportunistic infections, has also increased.

The devices division, dealing with condoms and rubber gloves, has increased as well, and with the problems in the blood supply in the inspection of the plants, we also have increased the numbers in the field.

As I return to the chair, I would like to focus now on clinical endpoints and some of the other issues. One of the most critical things facing us, in our opinion, is understanding the appropriate clinical endpoints. There is a myth that abounds in the land that FDA requires death as endpoint, or some other Draconian degree of analysis. Also, there is a myth that all trials must be placebo-controlled. That is not true. There is a myth that we cannot rely on historical data. That is not true.

But we have found, as the Institute of Medicine has stated, that by and large, the shortest path to a drug evaluation is a well-constructed placebo-controlled trial.

In the case of the last treatment IND on aerosolized pentamidine, however, that was a case in which there were three graded doses. One group received 30 milligrams twice a month; another, 150 milligrams twice a month; and another, 300 once a month. It was possible through this graded dose to evaluate the information and get a treatment IND without a placebo control.

But the clinical endpoints issue is in great need of analysis. We have called upon the Institute of Medicine, the Advisory Committee of the National Institute of Allergy and Infectious Diseases, and a new working group between NIH and FDA to try to deal with this.

The CHAIRMAN. Could I just ask you, Dr. Young, with regard to pentamidine, there are as I understand a number of FDA-approved drug protocols which prohibit any medication to prevent pneumonia.

[Information supplied follows:]

HIV Trials Excluding PCP Prophylaxis

1) Phase I/II Open Label Pharmacokinetics/Safety Trial
AZT & Alpha Interferon & GM-CSF

Indication: HIV Infection
Status: Active Recruitment
Number of Subjects: 30
Trial Duration: 16 weeks

PI: Richard Davey
National Institutes of Health

2) Phase III 3-arm Controlled Trial
AZT & Alpha Interferon

Indication: HIV+ Symptomatic
Status: Active Recruitment
Number of Subjects: 180
Trial Duration: Open

PI: Clifford Lane
National Institutes of Health

3) Phase III Double Blind Placebo Controlled Trial ACTG 051
AZT & Gammaglobulin

Indication: Pediatric Symptomatic HIV Infection
Status: Active Recruitment
Number of Subjects: 250
Trial Duration: 2 years

Sponsor: NIAID, AIDS Clinical Trials Unit (ACTG)

4) Phase I Dosing/Pharmacokinetics Trial
Alpha Interferon & Interleukin-2

Indication: HIV Infection
Status: Active Recruitment
Number of Subjects: 16
Trial Duration: 8 weeks

PI: Steven Schnittman
National Institutes of Health

5) Phase III Double Blind Placebo Controlled Trial
Azidothymidine

Indication: HIV+ Symptomatic/ARC
Status: Active Recruitment
Number of Subjects: 440
Trial Duration: 3 years

PI: Michael Simberkoff
Manhattan Veterans Administration Hospital

6) Phase I Open Label IV Safety/Tolerance Trial
Azidothymidine

Indication: AIDS/ARC
Status: Active Recruitment
Number of Subjects: 40
Trial Duration: 4 weeks

PI: Stephen Greenberg
Baylor College of Medicine
Texas Medical Center

7) Pharmacokinetics/Tolerance Trial ACTG 055
Azidothymidine & Methadone

Indication: AIDS/ARC on Methadone
Status: Protocol Final
Number of Subjects: 16
Trial Duration: 14 days

Sponsor: NIAID, AIDS Clinical Trials Group (ACTG)

8) Phase III Double Blind Placebo Controlled Trial
Azidothymidine

Indication: HIV+ Asymptomatic/PGL
Status: Active Recruitment
Number of Subjects: 600
Trial Duration: 3 years

Sponsor: Burroughs Wellcome

9) Phase I Open Label Dose Ranging Trial
Beta Interferon

Indication: HIV Infection/ARC
Status: Active Recruitment
Number of Subjects: 15
Trial Duration: 16 weeks

PI: Frank Graziano
University of Wisconsin Medical Center

10) Phase I Dose Ranging Trial ACTG 034
Ribavirin

Indication: AIDS/ARC
Status: Active Recruitment
Number of Subjects: 96
Trial Duration: 32 weeks

Sponsor: NIAID, AIDS Clinical Trials Group (ACTG)

11) Phase II/III Double Blind Placebo Controlled Trial
AZT & Acyclovir

Indication: ARC
Status: Active Recruitment
Number of Subjects: 600
Trial Duration: 2 years

Sponsor: Burroughs Wellcome

The CHAIRMAN. Do they prohibit pentamidine as well in these situations?

Dr. YOUNG. I think the protocols that you are speaking of are protocols that had been approved before the treatment IND was in place. Now the treatment IND for aerosolized pentamidine has been approved, and the drug has been shown to be a good preventative in people who have had a previous infection with pneumocystis carinii pneumonia as well as a good primary prevention treatment for people with T-cells below 200. I have communicated this to Dr. Fauci, and he will be evaluating many of these protocols and updating his INDs. We have not received that update yet, but I would anticipate that since this is now a recognized therapy, that that will be taken into consideration. In my professional opinion, it should be.

The CHAIRMAN. That is what I am driving at. Can you give us an assurance that all of the protocols will be reviewed?

Dr. YOUNG. I had requested that Dr. Fauci review those in view of the approval that we had for the treatment IND.

The CHAIRMAN. What did you hear from Dr. Fauci? Has he indicated he would do that?

Dr. YOUNG. We are in constant communication, and I know he is looking at these protocols now.

The CHAIRMAN. Is that a "yes" or a "no"?

Dr. YOUNG. That is a "yes."

The CHAIRMAN. He is going to—because obviously, as you well understand, there is an extraordinary medical/ethical issue involved in this as well as clearly a health issue. I would appreciate it if you could inquire from Dr. Fauci and get some written response that we can make a part of this record, because this is a matter of enormous importance and significance. It obviously has to be with regard to the agency as well as to the scores of people who are involved.

Dr. YOUNG. Absolutely. I would be delighted to do so, because it has been my position that when a new drug therapy is brought forward that it has to be included in these protocols, and they have to be dynamic protocols rather than rigid monuments set in letters of gold on tablets of jade; that does not work.

[Information supplied follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

February 14, 1989

Anthony S. Fauci, M.D.
National Institute of Allergy
and Infectious Diseases
National Institutes of Health
Bethesda, Maryland

Dear Tony:

This is in follow-up to our recent telephone conversation. As you know, at the AIDS hearing before the Senate Committee on Labor and Human Resources on February 7, I informed the Committee that the Food and Drug Administration had just approved the use of aerosolized pentamidine under FDA's Treatment IND regulations.

Chairman Kennedy expressed his concern to me that AIDS studies currently underway may not allow the use of other experimental products by study participants. He asked if I would formally request that the protocols for the various AIDS therapies that are underway at NIH be reviewed to determine whether or not aerosolized pentamidine should be permitted now that it has been approved for widespread use under a Treatment IND. I am therefore requesting that you have these protocols reviewed and inform me of the results.

I look forward to hearing from you on this most important issue.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner Food and Drugs

The CHAIRMAN. The clinical endpoints, Senator, are very important, and we are working on these. We do have a workshop scheduled with NIAID, and we will be looking at that in great depth.

The last point that I would call to your attention in my written testimony has to do with the very important issue of protection through risk reduction for individuals who may be exposed to AIDS occupationally. We are doing this, for example, through analysis of surgical and examination gloves.

We have had substantial problems in dealing with this, but I am pleased to inform you we now have a new test devised to examine the gloves; we are working on a regulation and new standards because there is real concern on the part of medical and nursing practitioners that there be the maximum protection afforded that is humanly possible.

Our standards will be somewhat lower than for condoms; instead of four leaks per thousand allowable, it will be closer to 25 and 40 for surgical and for examination gloves respectively, but we believe that this takes account of the relative risks, and we are continuing to evaluate that. That has been a great concern of the health profession.

Senator HATCH. Dr. Young, as a matter of fact, aren't a lot of the gloves that are imported in this country are defective?

Dr. YOUNG. Yes, we have found that to be true, Senator Hatch. In fact one of the problems that we had in using even the 25 leaks per 1,000 standard was that we had some gloves coming in from the Far East where 100 percent of the lots leaked, and the rate of leakage in gloves was alarmingly high. We have taken regulatory action while we are developing this standard. We are very concerned about the protection of the health workers.

In fact that is one of our problems; as we have dealt with our resources, we have continued to divert resources from the other parts of the agency to meet this need. For example, we have taken people from our flow cardiovascular devices area and diverted them to the glove area because it is such a high priority.

The CHAIRMAN. Please continue.

Dr. YOUNG. And finally, Mr. Chairman, I would say that we are working with computer-assisted NDAs, so that information can be obtained as rapidly, with computer assistance. That is clearly outlined in my testimony.

With regard to the law that you and Senator Hatch led, S. 2889, we have worked very vigorously on implementing the clinical databank. Fortunately, Dr. Parkman already had a contract for automating his license and IND files. We were able to use that same contract and divert those resources to work on the AIDS databank. We have much of the data in; the hardware and software are in place, and we are prepared to transmit this information to the Public Health Service.

We are also drafting a letter to be sent to manufacturers, requesting that not only when the efficacy trials are underway, but earlier, they voluntarily allow us to release these data. And only 13 percent of the trials are not released at this time.

The CHAIRMAN. You refer to that on page 5 of your testimony, and that was a key element in the legislation. In the testimony you

say, "computerized treatment drug registry is being established"—can you tell us where and when and who is running it?

Dr. YOUNG. Yes. Fundamentally, what we are doing is as follows—and I will be happy to have Dr. Parkman fill in any of the blanks, because he is our AIDS coordinator in FDA.

We have taken a contract that he was working on in a different subject, and now are using this completely for the clinical data registry. We used $500,000 that we were going to spend on automation of the general license files for INDs and biologics.

We have selected a contractor. About 50 percent of the data are entered already. The software and hardware are available for that. We will be able to transmit this to the Public Health Service.

We also are drafting a letter to go to every manufacturer of drugs and biologics in the Nation, asking them to allow us to release earlier than the efficacy trials—which you had highlighted in the bill—all of the information on the ongoing trial.

The data will show the name of the drug, the sponsor, and the general parameters of inclusion in the clinical trials; it will provide a follow-up on the efficacy; and we are asking that each company have an FDA liaison person who will work with FDA and with incoming inquiries on each study.

The CHAIRMAN. Will they have a phone number, with a doctor, so that patients can contact?

Dr. YOUNG. Yes, they will. Each company will be required in following this through to give us the name of an individual within that company who will be the standby individual.

We are working on the efficacy algorithm so that we can determine when an efficacy trial is in place. If there is an end-of-Phase-I conference, that would be sufficient for saying there is an efficacy trial; an end-of-Phase-II conference, similarly, or a trial where there are efficacy standards in place.

So we are well along on this implementation, and I am pleased that Dr. Parkman was able to get this up and running so fast.

Paul, would you like to add anything further on that?

Dr. PARKMAN. No. I think you covered it pretty well, Dr. Young.

There is a relationship with other parts of the Public Health Service in this area, with the National AIDS Program Office, the National Institutes of Health, and the National Library of Medicine, and the Centers for Disease Control. We are currently in the process of coordinating this effort with these other Government agencies.

Dr. YOUNG. I have been pleased with the rate of progress. We really got this one off the ground and running fast.

That concludes my comments, Mr. Chairman.

[The prepared statement of Dr. Young (with an attachment) follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

FRANK E. YOUNG, M.D., PH.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

FEBRUARY 7, 1989

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

I am pleased to be here today to discuss the Food and Drug Administration's (FDA) activities relative to the AIDS epidemic.

As you know, FDA's role in combatting AIDS is based primarily on our responsibility for the premarket review of new drugs and biologics, including vaccines, and medical devices. The evaluation of therapies for AIDS is our highest priority and the greatest point of intensity within the Agency. We are also responsible for the safety of the blood supply through licensure and inspection of blood and plasma collecting facilities, development of regulations for the manufacture of blood products and licensure of the products themselves.

Important management and regulatory initiatives have been undertaken resulting in identifiable progress in the regulation of new drugs and biologics. Specifically, we have modified our drug approval procedures extensively in the last four years, improving our review of therapies for AIDS and other serious diseases; a major reorganization has been accomplished; new management initiatives have been implemented; regulatory requirements have been simplified; backlogs in drug reviews have been greatly reduced; increases have been made in the number of trained personnel; new technologies have been incorporated into the regulatory process; the first drug for the treatment of AIDS (zidovudine or AZT) has been approved; and the first drug and biological products of biotechnology have been successfully introduced.

We have also initiated the practice of annual inspections of blood banks and plasma collection facilities. Increased efforts have been directed toward improving the safety and quality of AIDS-related medical devices. In addition, we have a number of outreach activities underway both with the AIDS community and the physicians who care for AIDS patients to establish the cooperation and communication needed to be responsive to the needs of people who are HIV positive.

I want to emphasize that the significant changes to streamline the drug review process have been made without sacrificing our statutory requirements of safety and efficacy. Our recent regulation in response to the request of then Vice President Bush promises to accelerate the evaluation of drugs and biologics for the desperately ill. The review process has considerable flexibility, and allows FDA to make sound scientific judgments concerning the risks and benefits of new therapies. When FDA reviews AIDS therapies, the life-threatening nature of the disease is a significant factor in the risk-benefit evaluation.

As I have noted previously, despite all our efforts, it is no easy task to review new AIDS therapies. HIV is a complex etiologic agent. As with all new drug research, because of problems with safety and effectiveness observed by the sponsors during clinical trials, only a small number of approved products will result from the many Investigational New Drug Applications that are submitted to FDA.

However, we are neither discouraged nor complacent. Improving the quality and timeliness of the review process for drugs and biologics continues to be one of FDA's highest priorities. As Commissioner, I pledge that FDA will continue to do all it can to ensure that important medical advances reach the desperately ill as soon as possible.

I would now like to discuss briefly the management and regulatory initiatives we have undertaken. I will describe in more detail the new regulations to streamline the drug approval process, discuss our efforts to define clinical endpoints for AIDS therapies, update you on the status of these therapies, as well as our efforts in the area of medical devices and blood safety and, finally, address the issues you raised in your letter of invitation to the hearing.

MANAGEMENT AND REGULATORY INITIATIVES

As we discussed at your hearing last July, a number of management and regulatory initiatives were implemented to improve the efficiency of the drug review system. In addition to the organizational changes we described then, the following other improvements have been accomplished:

-- The NDA Rewrite of the new drug application regulations, published in February 1985, was implemented to clarify and streamline the application process for new drug sponsors. Fourteen sets of guidelines have been published to aid sponsors in understanding how to complete those applications. Most

recently, we have issued a guideline for the clinical and statistical sections of an NDA which gives detailed guidance on putting together an application. As a result, we have already seen a significant reduction in the size of submissions for certain types of drugs (approximately 55 percent in one of our reviewing divisions).

-- The IND Rewrite of regulations governing drug testing was published in March 1987, with the goals of helping drug sponsors conduct better studies of promising new drugs, of giving researchers more freedom in designing studies, and of encouraging closer cooperation between drug sponsors and FDA.

-- Treatment INDs were authorized formally in regulations for the first time in May 1987 to permit widespread use of investigational drugs for desperately ill patients; and nine treatment INDs have been approved. Two of the drugs granted treatment IND status have since been approved (Attachment 1).

-- We have recently implemented regulations to expedite the development and approval of drugs for AIDS and other life-threatening or severely debilitating illnesses. I will return to these shortly.

-- Pilot efforts have begun to utilize the electronic submission of new drug application data.

-- Management information systems have been updated and automated within FDA to improve the efficiency and accountability of the drug review system.

-- Working groups have been established with the Institute of Medicine and the Pharmaceutical Manufacturers Association to gather ideas about ways to improve the drug review process.

-- A computerized Treatment Drug Registry designed to provide information on clinical trials is being established.

-- A periodic report describing advances in AIDS therapies is prepared by the Office of Public Affairs. I will submit the most recent January 30 report for the record

-- An AIDS Electronic Bulletin Board to disseminate information about Agency AIDS activities is under development.

-- Support and training related to Community Based Research is being provided which will facilitate quicker access to broader-based, accurate data on drugs of interest to the AIDS community.

-- AIDS field coordinators have been designated in each of FDA's 22 districts to provide patients, clinicians, activists, and other interested parties direct access to FDA at the local level.

I will discuss our efforts to automate our drug review process in more detail later in my testimony.

THE NEW REGULATIONS

I would now like to describe our new regulations as well as provide an update on the status of AIDS therapies. Last fall, FDA announced the immediate implementation of new regulations designed to make promising therapies available sooner for patients with life-threatening and severely debilitating diseases. As I mentioned earlier, the plan was developed at the request of then Vice President Bush in his capacity as Chairman of the President's Task Force on Regulatory Relief (Attachment 2).

Ordinarily, the testing of drugs in humans takes from 3 to 7 years. For treatments for AIDS and other life-threatening conditions, we want to reduce that time to the bare minimum needed to assess safety and effectiveness, as we did with zidovudine.

The element of the plan I want to emphasize today is the need for consultation between FDA and sponsors early on as well as throughout the drug development process. Adequate protocol design and development is crucial. Only in this way can we get the well-designed, well-controlled studies that will make this plan work. By preventing false starts and wasted effort, we can do much to save time and cut costs. These regulations also provide for focused regulatory research

so that the Agency can apply its scientific base to help sponsors with rate limiting research steps.

FDA's goal is to be able to reach a scientifically defensible decision to approve or disapprove marketing of drugs intended to improve the outcome in diseases such as AIDS, based on the results of well-designed phase 2 controlled trials. In this way, it is hoped that important drugs and biologics will be developed in the minimum time, just as zidovudine was.

When FDA consults with sponsors during the preclinical stage, we can facilitate the start of clinical trials as early as possible, thereby reducing potential barriers to innovation at this important stage of new pharmaceutical development, and limit animal studies to the minimum required to ensure safety.

At the end of early (phase 1) clinical testing, FDA and the sponsor will seek to reach agreement on the proper design of phase 2 controlled clinical trials. The goal of these trials is to have sufficient data on the product's safety and effectiveness to support a decision on its approvability for marketing. Zidovudine is an example of how such properly designed trials resulted in approval of the product.

These new regulations recognize that physicians and patients are generally willing to accept greater risks or side-effects from products that provide effective treatment for life-threatening or severely

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debilitating diseases. The benefits clearly make the risks involved worth taking.

If the preliminary analysis of test results appears promising, we may encourage a treatment IND. Such a treatment protocol, if submitted and granted, would allow widespread distribution of the drug while the new drug application is being reviewed.

Once phase 2 testing and analysis is completed by the sponsor and a marketing application is submitted, the Agency has the difficult task of considering whether the benefits of the drug outweigh the known and potential risks in satisfying the statutory standard for safety and effectiveness. Here, we have to take into consideration the severity of the disease and the absence of satisfactory alternative therapy.

Finally, when approval or licensing of a product is being granted, FDA may work with the sponsor to determine which postmarketing studies should be done. Such studies would help to determine rare long-term side-effects, reactions in particular population groups such as the elderly, and appropriate dosage changes and potential new indications.

CLINICAL ENDPOINTS

The issue of clinical endpoints and criteria for demonstration of efficacy has been particularly troublesome for AIDS therapies. FDA has, therefore, made a concentrated effort to address the issue of selection and definition of endpoints to assess the effectiveness of

experimental drugs in controlled clinical trials for HIV-infection and its associated complications. At the outset I wish to emphasize that FDA does not regard reduction in mortality as the sole endpoint in clinical trials. However, the complexity, chronic nature and variable rate of progression of the disease, has made reliance on surrogate markers, either clinical or laboratory, particularly problematic. Unfortunately, we simply do not yet have the data base that will allow us to use changes in laboratory tests to predict when a drug is bringing the underlying disease under control.

In HIV infection, the same endpoint criteria cannot be applied to all stages and for all aspects of the disease. Specific criteria must be modified as more is learned about the natural history of the disease, as more information is developed regarding the utility of laboratory markers or other near-term correlates of disease progression, and as new drugs are shown to be effective and become widely used to treat the complications of HIV infection and the underlying retroviral infection itself. Furthermore, as exemplified by the data in the recent trial with aerosolized pentamidine, we can evaluate results with different doses of drugs instead of placebos.

Clearly, we understand the need for flexibility and openness to change in the specification of efficacy criteria. To this end, in response to a request from President Bush, a National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS has been established. One of the charges of this committee is to determine what should be the appropriate endpoints for assessing effectiveness of new

agents for treatment of AIDS. FDA and NIH staff have testified before this committee and are providing materials to assist the committee in this effort. In addition, the Division of Antiviral Drug Products (DAVDP) has convened a series of internal meetings to explore the alternatives for clinical endpoints and the design of pivotal efficacy studies for new antiretroviral agents. We are also planning, in conjunction with our colleagues at NIH, a workshop to discuss the current working proposals developed in our internal meetings. The object of the workshop is to elicit comments and constructive criticism and, we hope, to emerge with a consensus on the most appropriate way to proceed.

CURRENT STATUS OF AIDS THERAPIES

Let me now update you on the number of product applications currently in our system. As of January 1, 1989, FDA had approved 213 investigational new drug applications (INDs) to test 146 new AIDS drugs, biologics, vaccines, and diagnostics in humans (Attachment 3). The 213 approved IND applications include:

43 for antiviral drugs
70 for immunomodulators
4 for vaccines
6 for antineoplastics
41 for drugs to treat opportunistic infections
49 for diagnostics

We now receive close to 10 applications each month. This surge in research has come from both Federal and private sources. To date most of these studies have been of "off the shelf" compounds originally synthesized without detailed knowledge of the biology of HIV. We believe we are just beginning to see the clinical investigation of drugs that are designed specifically for AIDS, and we believe FDA's workload in this area will continue to increase (Attachments 4 & 5).

Zidovudine remains the only approved drug to treat AIDS directly. However, a variety of other drugs, some similar to zidovudine others quite different, are being tested for direct effects on AIDS. In addition, an intense search is underway to find drugs to treat opportunistic infections and cancers that are often fatal to AIDS patients. The injectable form of the drug pentamidine to treat Pneumocystis carinii pneumonia (PCP) was approved quickly, in about six months. This past November, the Agency approved alpha interferon to treat Kaposi's sarcoma, based in part on a study by scientists at the National Institute of Allergy and Infectious Diseases (NIAID). NIAID is also conducting studies comparing treatment with alpha interferon plus zidovudine to treatment with zidovudine or alpha interferon alone. We anticipate that combination therapies will become increasingly more important in the treatment of AIDS, in the same way that they have in the treatment of some other diseases such as tuberculosis and many cancers.

Let me now turn to treatment INDs:

Three treatment INDs for AIDS-related conditions have been approved. Trimetrexate was the first, approved for expanded distribution in February 1988, to treat PCP. The treatment IND's sponsor is NIAID.

The second treatment IND was granted for ganciclovir on November 30, 1988 to treat patients with cytomegalovirus retinitis, a disease with infections that are immediately sight-threatening. Controlled clinical trials are underway for patients whose sight is not immediately threatened, however enrollment is slow. NIAID is also sponsoring the treatment IND while the Syntex Corporation is supplying the drug. Currently we are reviewing the original data submission and other information that will be obtained in colloboration with NIAID.

A third treatment IND--aerosolized pentamidine used every month to reduce the chance that severely immuno-compromised patients will develop PCP was approved yesterday.

The treatment IND was developed on the basis of a clinical study of 408 HIV-infected patients at high risk for developing PCP, that is, AIDS patients with a history of one or more episodes of PCP, and other AIDS and advanced ARC patients with CD4 counts less than 200 cubic millimeters. The clinical study compared the safety and efficacy of aerosolized pentamidine, administered through the Respirgard II nebulizer, at 30 mg every two weeks, 150 mg every two weeks or 300 mg every four weeks. The study results indicate that aerosolized

pentamidine when administered at 300 mg every four weeks via the Respirgard II nebulizer, while not providing complete protection against PCP, did demonstrate the ability to significantly reduce the incidence of this pneumonia by half. However, aerosolized pentamidine is not without risk. It can provoke severe wheezing and coughing. The long-term risks associated with aerosolized pentamidine are unknown, and therefore is not recommended for HIV-infected patients who are not at appreciable near-term risk of developing PCP, i.e., those with CD4 counts greater than 200 cubic millimeters.

The manufacturer, Lyphomed, Inc., has also filed a new drug application with FDA seeking marketing approval for this version of the drug which FDA is reviewing.

As you know, I am committed to the treatment IND program. In each of these three instances, I tried to provide personal encouragement and support to the individual sponsors. I plan to continue meeting with other manufacturers regarding additional AIDS therapies which appear to be promising.

MEDICAL DEVICES

I would like to discuss for a moment the Agency's AIDS activities with respect to medical devices, specifically gloves and condoms.

In regard to gloves, we are involved in a two stage approach to address the quality of both surgical and patient examination gloves. Surgeon's

gloves have always been subject to both premarket notification procedures and good manufacturing practices regulations. However, when the Agency classified patient examination gloves in 1980, we exempted manufacturers from both premarket notification procedures and the Current Good Manufacturing Practices regulations. FDA granted these exemptions because no adverse experiences had been related to these devices. Since that time, however, AIDS has become a major health problem and although HIV is contracted primarily through sexual contact, a number of cases have been contracted through contact with infected blood or blood products. Additionally, HIV has also been isolated from body fluids such as saliva and tears and body excretions such as urine. Health care workers, whose activities involve contact with blood or other bodily fluids or excretions, have come to depend on patient examination gloves to provide protection against contamination with the AIDS virus. As a result, demand for these gloves continues to grow. Patient examination gloves can provide an effective barrier only if the gloves are intact, that is, as long as they do not contain or develop holes while being used.

Therefore, I am pleased to report that FDA has recently issued a final rule revoking the exemption from premarket notification procedures and the Current Good Manufacturing Practices regulations for patient examination gloves. We believe that this action will help provide assurance that manufacturers provide an acceptable manufacturing quality level for these gloves. The revocation of the premarket notification exemption will also allow the Agency to better monitor the introduction of these devices into commerce by manufacturers and

importers. We are also in the final stages of establishing the second part of our effort to address glove quality with a program for sampling and testing both surgical and patient examination gloves, similar to the Agency's ongoing program with condoms. Both of these programs have involved the Agency in developing appropriate test methodologies.

With respect to condoms, FDA has tested over 180,000 condoms to date. These examinations have resulted in a number of product recalls and import detentions. We are now focusing strong efforts on the review of new barrier devices to the sexual transmission of the AIDS virus, as well as assessing the role of medical devices in the potential transmission of the virus.

Let me assure you that FDA is committed to continuing efforts to both thoroughly and fairly review device applications for products intended to reduce infection by HIV and to make use of our resources and regulatory authority to help assure that devices used for AIDS prevention and protection are safe and effective for that purpose.

BLOOD SAFETY

As I mentioned earlier, FDA also has the responsibility for overseeing the safety of the Nation's blood supply.

Following a number of recalls of blood and blood plasma last March because of possible AIDS and hepatitis contamination, FDA made a commitment to inspect every U.S. blood bank and plasma center by the

end of the 1988 fiscal year, which ended September 30. These inspections included a thorough review of facility records of blood handling over previous months. In fiscal year 1988 FDA inspected 2,424 blood banks and plasmapheresis centers or 100 percent of all such FDA-regulated facilities in the United States. We found a number of technical errors that required correction. Thus, FDA worked with blood and plasma organizations such as the American Association of Blood Banks, the American Blood Resources Association, the American Red Cross (ARC), and the Council for Community Blood Centers to improve procedures and eliminate errors. In fact, last September, ARC and FDA signed an agreement under which the Red Cross is modifying its operations nationwide. I will also submit a copy of this agreement for the record. FDA's inspection program will continue to focus on the procedures used by the blood and plasma industry in donor screening, testing for hepatitis and HIV antibodies, and procedures for quarantine and destruction of unsuitable blood products.

I would now like to discuss the other issues you raised in your letter.

COMPUTER ASSISTED NEW DRUG APPLICATIONS

We have begun to expand the use of technology to enhance the review of NDA's by inviting firms to submit portions of their NDA's in automated form. These partial submissions are coming to us on various magnetic media, optical disks, and via telephone connections. Although we have

not yet received an entire NDA electronically, we anticipate that this could occur in the foreseeable future.

Currently, we are receiving nearly all of the statistical submissions associated with effectiveness and biopharmaceutics data for kinetic reviews in electronic form. We provide a pre-programmed floppy disc that enables the firm to add data and to have both FDA and the sponsor rapidly analyze the information through a number of programs. In addition, we have experience with about 30 automated submissions of clinical data and are beginning to explore the potential for automated submission and review of the chemistry, pharmacology and microbiology sections of NDA's. This includes working actively with sponsors to submit the preclinical technology data which supports clinical studies, by computer.

Until now, there have been no submissions of electronic or computer assisted NDA's for AIDS products. However, we have been able to equip the Division of Antiviral Drug Products sufficiently, such that they are prepared to accept and review a computer-assisted NDA as soon as the first one arrives.

Based on our experience with the NDA's we have reviewed, it is already apparent that there are benefits to automated submissions. First, because of the newness of the procedures, we have had to work closely with the submitting firm at an early stage in the NDA development process. Having that dialogue has been beneficial.

Another advantage is that this approach provides our medical reviewers with the capability to make direct inquiries about the clinical data received and obtain a response within minutes thereby precluding needless delays. For example, a reviewer might need to identify all patients in clinical trials with liver dysfunction. Previously an inquiry to obtain such information could take a comparatively long time to be responded to by the sponsoring firm because of the need to go through clinical case reports to respond to the request for additional information. With computer-assisted NDA, it is possible to almost instantly identify all patients with liver enzymes elevated three times the baseline and with fever or rash-- or any other set of parameters. These benefits clearly will, over time, help us reduce our NDA review time.

STATUS OF AIDS ON-LINE TRACKING SYSTEM

As part of the Agency's management initiatives to expedite the review and approval of AIDS and AIDS-related applications, FDA is developing an on-line tracking system for AIDS review activities. At this time, we have selected both the hardware and software; processing programs have been written; over 50 percent of the data have been entered into the system; and a contractor has been selected to input the remaining data. In the meantime, we are using less sophisticated systems, but I can assure you that we have current data on every pending application. This has enabled the Office of the Commissioner, and other senior officials to track the progress of the clinical trials.

RECRUITMENT

As you mentioned in your letter of invitation, it is absolutely essential that we recruit the best scientific and management talent available. A substantial effort is underway in this regard. In June 1988, the position of recruitment manager in FDA was established. This position has responsibility for coordinating and managing the process of recruiting new physicians into the Agency. Our recruitment program has established a wide network of contacts and applications have been generated through attendance at job fairs and scientific meetings, paid advertisements placed in medical journals, contacts made by the current staff, and college and university site visits. In the past 8 months, 9 medical reviewers for AIDS-related work have been hired from such diverse backgrounds as hospitals, academia, the research community, the pharmaceutical industry, other Government agencies, and fellowship and graduate programs.

UTILIZATION OF RESOURCES

In your letter you also asked for more information about the employee resources (staff years) FDA has budgeted for AIDS work in 1989 and how they will be used. Because the events surrounding the AIDS epidemic are so dynamic, accurately predicting the resource demands that it places on FDA has been impossible. Events unfold faster than we forecast, and unexpected findings often lead to resource expenditures never anticipated. For example, in 1988, FDA expected to spend 127 staff years on various AIDS related work. In fact, because of work

that became essential to protect the safety of the Nation's blood supply, and unanticipated problems with condom and glove quality, we actually spent substantially more staff years on AIDS related work.

The budget forecasts that FDA will spend 323 staff years on AIDS in 1989 and 504 staff years in 1990. Of these, 314 staff years have been added to FDA since 1984. Clearly, our commitment continues to accelerate.

FDA's resources related to AIDS are deployed among several components of the Agency and have been increasing over time. Within the Center for Drug Evaluation and Research (CDER), staff years related to AIDS are devoted to: the review and evaluation of applications for approval of newly-developed AIDS drugs; the provision of consultation to drug sponsors regarding preclinical studies and clinical trial design and conduct, and the guidance on efficient drug development and application preparation; the review and evaluation of requests for treatment use of investigational drugs; the conduct of postmarketing surveillance to monitor product performance, regulatory research on aspects of the preclinical, chemical manufacturing, and clinical phases of drug development; and, investigations of drug products marketed under fraudulent claims related to AIDS and AIDS-related diseases.

The AIDS-related work effort within the Center for Biologics Evaluation and Research (CBER) includes: the review and evaluation of applications for approval of newly-developed biologic therapeutics for AIDS; applied research into improved HIV detection methodology, HIV

suppression techniques, and vaccine development; the provision of consultation to sponsors of biologic products regarding preclinical studies and clinical trial design and conduct; the conduct of postmarketing surveillance; and the review of applications for licensure of products for screening blood donors and for other diagnostic uses.

Our Center for Devices and Radiological Health (CDRH) reviews and evaluates applications for approval of AIDS-related medical devices, such as surgical and patient examination gloves and condoms, conducts research into improvement of barrier effectiveness of AIDS- related products and develops new standards and guidelines for these products when needed.

In addition to our [illegible], FDA has field offices located throughout the country [illegible] activities in the field are concerned with investigations [illegible] health claims about products related to AIDS, annual inspections of all FDA-regulated blood donor facilities, inspections of the conduct of clinical trials of products related to AIDS, inspections of manufacturers and processors of AIDS-related medical devices; and product testing of AIDS-related drugs and devices to assure conformance with established standards.

The Office of the Commissioner provides overall direction and management for AIDS activities, as well as a variety of support activities for our AIDS program, including liaison with health professionals, consumer organizations and the AIDS community. It is

extremely important that we communicate effectively with people with AIDS, the health care providers and the general public.

FACILITIES

The largest number of employees dedicated to AIDS is in the Center of Biologics Evaluation and Research under the direction of Dr. Paul Parkman, the AIDS Coordinator for the Agency. Most of these employees are located in two buildings on the NIH campus. Because of our increased staffing for AIDS work, these buildings now house over 100 people more than they were designed for. The remaining CBER staff including the AIDS Coordination staff occupy offices in the Parklawn Building. To relieve this overcrowding and to accommodate essential new AIDS-related employees, construction of a new building has begun.

Fortunately, President Reagan's FY 1990 budget requested and Congress appropriated funds in Fiscal Year 1989 for us to build a new building next to the two buildings on the NIH campus. This building will eventually alleviate much of the space problem we are having on the NIH campus.

CONCLUSION

In conclusion, FDA's successful efforts over the past four years to streamline the drug and biologic review system show that FDA is an integral part of controlling the AIDS epidemic. We have the responsibility of assuring that new therapies are safe and effective

and are transferred expeditiously to the public. We cannot afford to fail on either count. Accordingly we have placed the evaluation of new therapies in general and AIDS in particular as one of FDA's highest priorities.

We are in the midst of a biomedical revolution that promises to change the face of medicine forever. The new biotechnology especially will have a large impact on the discovery and development of new therapeutic agents. Such change demands that we leave behind many of our old ideas of doing business, be proficient in the latest technology, and find new ways to work together within the scientific community. We must strengthen the partnership among academia, NIH, advocacy and community-based groups, the medical community, and industry so that we can work together to develop safe and effective new therapies in this time of change.

As a physician and as a person who has deep compassion for people with AIDS and other devastating illnesses, I am personally committed to ensuring that FDA does its part to aid in the design of clinical trials and the evaluation of safe and effective new therapies--real hope for the future.

We must also continue to vigilantly protect the Nation's blood supply. We must also aggressively pursue our efforts to insure the quality of AIDS-related medical device products in the marketplace. The task and the challenge are enormous. Even though the challenge is great, working together, I believe we will succeed.

This concludes my prepared testimony. I will be happy to answer any questions you may have.

Attachment 1

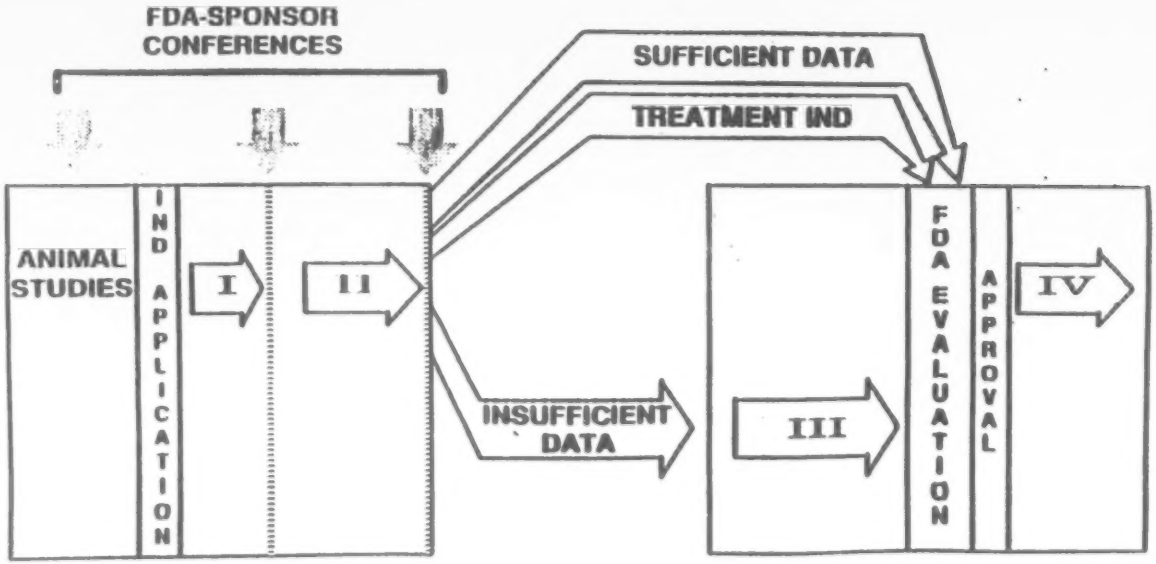
TREATMENT INDs

Drug/Biologic	Indication	Date Received	Allowed to Proceed	NDA Approved
Trimetrexate	AIDS patients with PCP intolerant to standard therapy	September 17, 1987	October 16, 1987	----
Cytomegalovirus Immune Globulin	Renal transplants (prevent cytomegalovirus infections)	September 21, 1987	October 19, 1987	----
Ifosfamide and mesna	Refractory germ cell carcinoma	November 30, 1987	December 24, 1987	December 30, 1988 (2 separate NDAs)
Clomipramine HCL (Anafranil)	Severe cases of obsessive compulsive disorder	May 10 & 12, 1988 (final receipt date)	June 3, 1988	----
Selegilene HCL (Eldepryl)	Severe Parkinsons's disease	May 20, 1988	June 16, 1988	----
Pentostatin	Refractory hairy cell leukemia	June 3, 1988	July 28, 1988	----
Teniposide	Relapsed or refractory acute Lymphoblastic Leukemia	September 12, 1988	October 7, 1988	----
Ganciclovir	CMV retinitis in AIDS patients	November 16, 1988	November 28, 1988	----
Aerosolized Pentamidine	Reduce occurrence of PCP in severely immuno-compromised AIDS patients	January 30, 1989	February 3, 1989	----

Attachment 2

DRUG DEVELOPMENT PROCESS

PRODUCTS FOR LIFE-THREATENING ILLNESSES

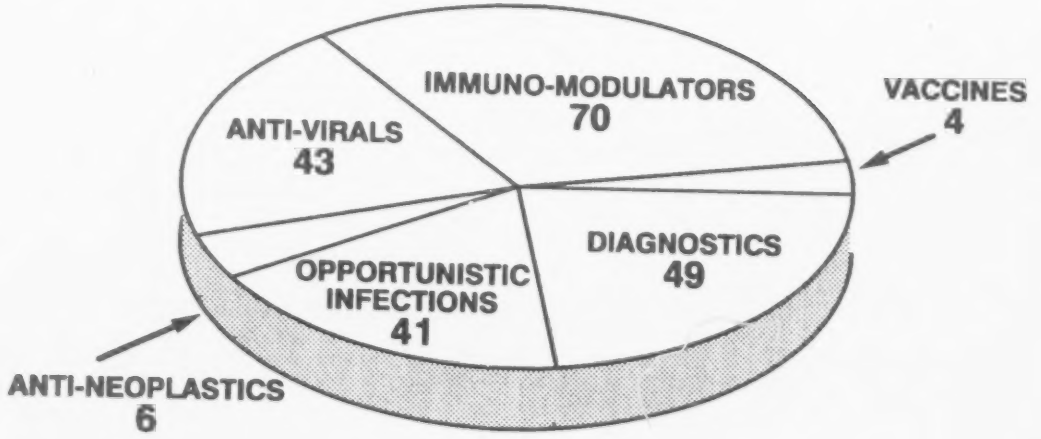


Attachment 3

AIDS INDs

TOTAL = 213

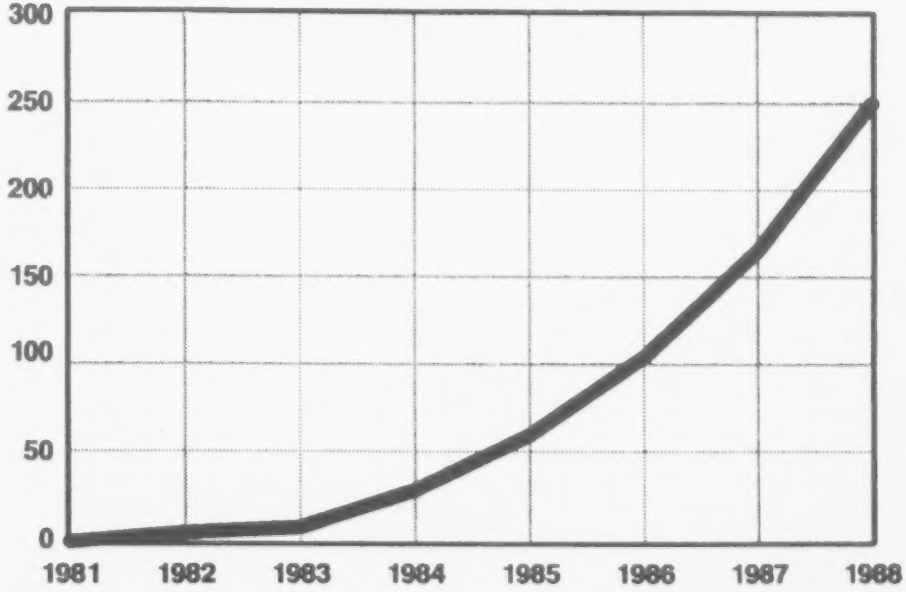
As of January 1, 1989



31-JAN-89

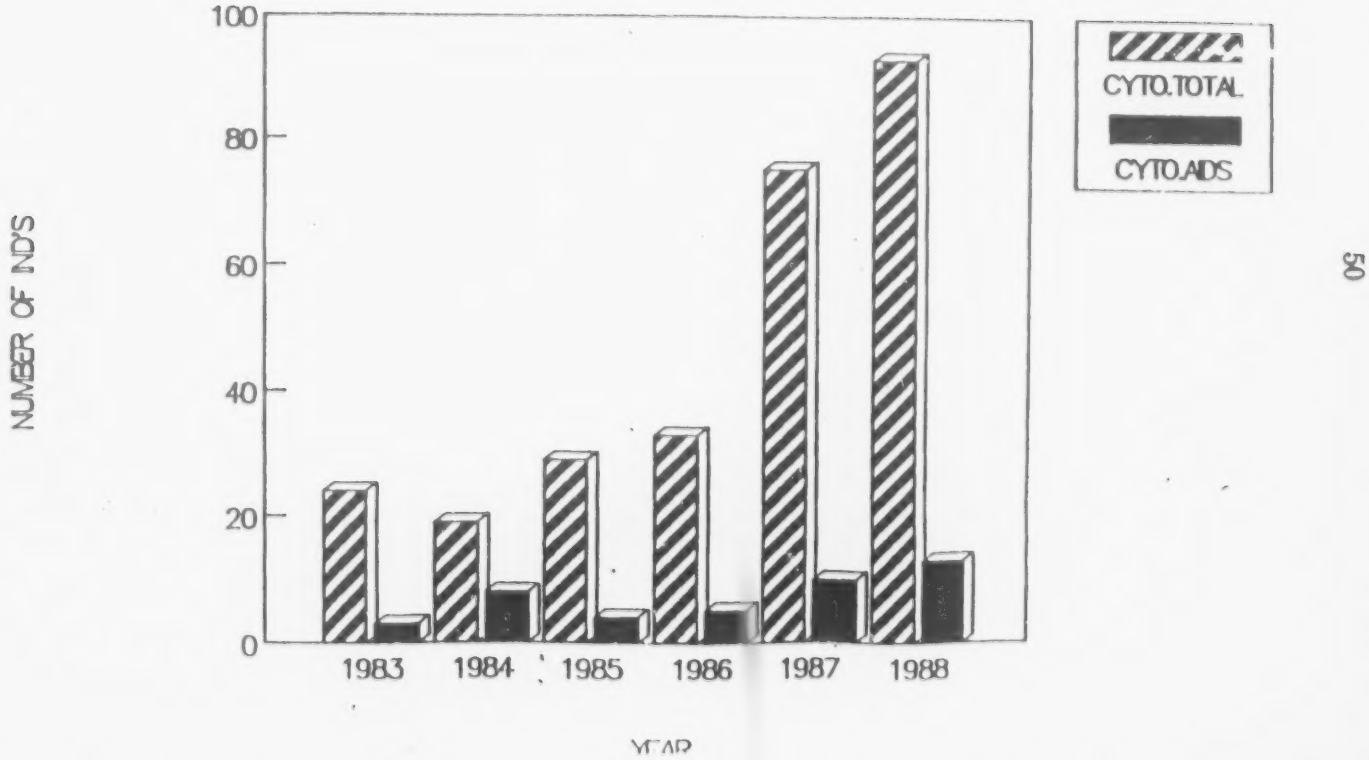
Attachment 4

AIDS INDs



Attachment 5

CYTOKINE BIOLOGY



Page 5
Line 10

Food and Drug Administration

Submission for the Record

Hearing Before The

Committee on Labor and Human Resources
United States Senate

February 7, 1989

FDA

Press Office
Food and Drug Administration
U.S. Department of Health and Human Services

NOTE TO CORRESPONDENTS/ AIDS UPDATE
Jan. 30, 1989

Brad Stone
(301) 443-3285

NEW STUDIES FOR EXPERIMENTAL AIDS DRUGS UNDERWAY

On Jan. 17, 1989, FDA gave permission for the clinical testing of a third version of recombinant soluble CD4 protein.

Normally, CD4 protein is found on the surface of T4 helper cells -- basic components of the body's immune system which are attacked by the AIDS virus. The AIDS virus enters the T4 cell through interaction with the CD4 protein and then destroys the host cell while using the cell's genetic material to replicate.

-MORE-

In theory, injecting relatively large quantities of CD4 proteins produced through recombinant DNA technology into AIDS-virus infected individuals might divert the AIDS virus in some measure away from the T4 cells and toward these decoy CD4 proteins. This diversion, if it occurs, might slow or prevent the replication of the AIDS virus and thereby delay or preempt progression of the disease.

SmithKline Beckman Corp. of Philadelphia, Pa., (215) 751-5166 will sponsor the new study at the Walter Reed Medical Center in Washington, D.C.. The first version of soluble CD4 protein to receive FDA permission for clinical testing is being developed by Genentech Inc. of San Francisco, Calif., (415) 266-1614 in conjunction with the National Cancer Institute (301) 496-6631. Another version of the CD4 protein developed by Biogen Inc of Cambridge, Mass., (617) 864-8900, was the second such agent to receive FDA permission for clinical testing.

Expanded clinical trials for foscarnet, an experimental drug for the treatment of cytomegalovirus retinitis -- an opportunistic viral infection that can cause blindness in AIDS patients -- are being sponsored by the drug's manufacturer, Astra Pharmaceutical Products Inc. of Westboro, Mass., in conjunction with the National Institute for Allergy and Infectious Diseases and the National Eye Institute. AIDS patients with the indicated conditions may qualify for the studies in these locations:

Houston, Texas -- All cytomegalovirus retinitis patients

Los Angeles, Calif. -- First episode cytomegalvirus retinitis patients

San Francisco, Calif. -- First episode cytomegalvirus retinitis patients

New York, N.Y. -- First episode cytomegalvirus retinitis patients

Bethesda, Md. -- First episode cytomegalvirus retinitis patients

AIDS patients and physicians interested in participating in one of these ongoing clinical studies may call Dr. Cheryl Karol of Astra Pharmaceutical Products at (508) 366-1100 ext 2370, from 9 a.m. to 5 p.m. EST, Monday through Friday.

The following may help answer questions about other potential AIDS therapies and vaccines now being studied. This information updates the Note to Correspondents/AIDS UPDATE, of Oct. 27, 1988.

NEW DRUG APPLICATIONS (NDAs)

FDA has given all potential AIDS drugs a 1-AA classification -- the highest priority -- in FDA's new drug review system. The agency's expedited review of zidovudine (marketed as Retrovir and more commonly known as AZT), which became the first approved treatment for AIDS, served as the prototype for the new 1-AA classification.

-MORE-

The agency reviewed and approved zidovudine's new drug application in less than four months -- 107 days -- after its submission.

There are no NDA's currently pending before the agency for drugs to directly treat AIDS.

INVESTIGATIONAL NEW DRUGS (INDs)

FDA has approved more than 100 on-going human studies to test potential AIDS drugs. In many cases, FDA has granted permission to begin these trials within five days of receiving an application. This was true, for example, of a recent requests by sponsors to test Interleukin-II and GM-CSF. (Unless FDA notifies a sponsor of problems within 30 days, a sponsor can go ahead with its research plan.)

At present, IND studies involve more than 40 different anti-viral or immuno-modulating drugs. Many trials are now investigating the use of two or more experimental therapies in combination.

Due to the intense public interest in AIDS, many of the sponsors of experimental AIDS therapies now undergoing FDA-sanctioned clinical testing have made some information about their therapies available. The following is a list of potential AIDS therapies publicly acknowledged by their sponsors to be now under study. Requests for additional information on any of these products should be directed to the IND sponsor.

INDs FOR EXPERIMENTAL ANTI-VIRAL AGENTS

EXPERIMENTAL TREATMENT	SPONSOR
DHEA	Elan Corp., Atlanta, Ga., (404) 534-8239
Carrisyn	Carrington Laboratories Inc., Irving, Texas (214) 541-2278

-MORE-

Ansamycin (rifabutin)	Adria Laboratories, Dublin, Ohio (614) 764-8100
Ribavirin	Viratek/ICN Pharmaceuticals, Costa Mesa, Calif. (800) 556-1937
ddC (Dideoxycytidine)	Hoffmann-La Roche Inc., Nutley, N.J. (201) 235-5000
	National Cancer Institute, Bethesda, Md. (301) 496-6631
ddA (Dideoxyadenosine)	National Cancer Institute, Bethesda, Md. (301) 496-6631
ddI (Dideoxyinosine)**	National Cancer Institute, Bethesda, Md. (301) 496-6631
	Bristol-Myers Laboratories Wallingford, Conn. (203) 284-6000
	National Inst. of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717
HPA-23	Rhone-Poulenc, Monmouth Junction, N.J. (201) 297-0100
AL 721	Matrix Laboratories, Fort Lee, N.J. (201) 944-0444
	National Inst. of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717
Dextran Sulfate (UA001)	Ueno Fine Chemicals Industry Ltd., New York, N.Y. (202) 452-8666
	National Inst. of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717
Foscarnet	National Inst. of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717
r-beta-ser Interferon*	Triton Biosciences, Alameda, Calif. (415) 769-5200

INDs FOR EXPERIMENTAL IMMUNO-MODULATING AGENTS

EXPERIMENTAL TREATMENT	SPONSOR
DTC (Imuthiol)	Merieux Institute, Miami, Fla. (305) 593-9577

-MORE-

Thymopentin	Immunobiology Research Inst., Annandale, N.J. (201) 730-1799
Peptide-T*	National Inst. of Mental Health, Bethesda, Md. (301) 443-4515
Isoprinosine	Newport Pharmaceuticals, Newport Beach, Calif. (714) 642-7511
Alpha Interferon*	Hoffmann-La Roche Inc., Nutley, N.J. (201) 235-5000
Gamma Interferon*	Genentech Inc., San Francisco, Calif. (415) 266-1000
Interleukin-II*	Hoffmann-La Roche Inc., Nutley, N.J. (201) 235-5000
CD4 Protein*	Genentech Inc., San Francisco, Calif. (415) 266-1614
	SmithKline Beckman Corp., Philadelphia, Pa (215) 751-5166
	Biogen, Inc. Cambridge, Mass. (617) 864-8900
Inactivated Polio Vaccine*	Connaught Laboratories Inc., Swiftwater, Pa. (717) 839-7187
r-GM-Colony Growth Stimulating Factor*	Sandoz Pharmaceuticals Corp. East Hanover, N.J. (201) 386-7500, and
	Schering-Plough Corp. Kenilworth, N.J. (201) 558-4000
r-Erythropoietin*	Ortho Pharmaceutical Corp. Raritan, N.J. (201) 218-6636

OPPORTUNISTIC INFECTION AND CANCER AGENTS

In addition to the effort to develop drugs to deal directly or indirectly with HIV itself, there is an intense search for drugs to treat opportunistic infections and cancers that are often lethal to AIDS patients who -- with a depleted immune system -- may be highly vulnerable to common, and normally non-fatal diseases.

-MORE-

Experimental drugs for these conditions include anti-infectives which will act directly against an infection, immuno-modulators to boost the body's own immune system and anti-neoplastics to act directly against cancers.

The most prevalent forms of opportunistic infections and cancers include:

Pneumocystis carinii pneumonia (PCP) -- a severe lung infection found in nearly 80 percent of all AIDS patients at some time during the course of the disease.

Candidiasis -- A fungal infection of the mouth and esophagus.

Kaposi's Sarcoma (KS) -- A malignant tumor condition common in AIDS patients.

Cytomegalovirus (CMV) -- An opportunistic viral infection that can cause blindness and/or death in AIDS patients.

There are a number of drugs which are either already approved or are being developed for these conditions. In Nov. 1988 two versions of alpha interferon were approved for the treatment of Kaposi's Sarcoma. Schering Corp. of Kenilworth, N.J., and Hoffmann-La Roche of Nutley, N.J., will market the slightly different molecular versions of the licensed interferon treatment under the Intron-A and Roferon brand names respectively.

Another example of an approved drug for an AIDS-related condition is the anti-infective drug pentamidine**, produced by LyphoMed Inc. of Rosemont, Ill., used in the treatment of PCP pneumonia. Using an expedited review procedure, FDA approved pentamidine for commercial marketing in just over six months.

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PENDING NEW DRUG APPLICATIONS (NDAs)

The following are drugs for AIDS-associated conditions that have pending new drug applications (NDAs):

NDA--EXPERIMENTAL ANTI-INFECTIVE AGENTS

EXPERIMENTAL TREATMENT	SPONSOR	INDICATION
ganciclovir (DHPG)	Syntex Corporation Palo Alto, Calif. (415) 855-5050	Cytomegalovirus/ life or sight threatening

NDA--EXPERIMENTAL IMMUNO-MODULATING AGENTS

EXPERIMENTAL TREATMENT	SPONSOR	INDICATION
None		

NDA--EXPERIMENTAL ANTI-NEOPLASTIC AGENTS

EXPERIMENTAL TREATMENT	SPONSOR	INDICATION
None		

INVESTIGATIONAL NEW DRUGS (INDs) FOR OPPORTUNISTIC INFECTIONS AND CANCERS

FDA has approved more than 80 on-going human studies to test potential drugs for opportunistic infections and cancers. At present these studies involve nearly 30 different agents. In several cases, separate human trials are being conducted with the same proposed AIDS therapy to test its effect on different AIDS conditions. Many trials are examining the use of the following experimental therapies in combination with the approved antiviral drug, zidovudine.

-MORE-

IND--EXPERIMENTAL ANTI-INFECTIVE AGENTS

EXPERIMENTAL AGENT	SPONSOR	INDICATION
Trimetrexate**	Warner-Lambert Company Morris Plains, N.J. (201) 540-2000	Pneumocystis carinii pneumonia (treatment)
	National Institute of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717	Pneumocystis carinii pneumonia (treatment)
Eflornithine (DMFO)**	Merrell-Dow Pharmaceuticals Inc. (513) 984-9111	Pneumocystis carinii pneumonia (treatment)
Aerosol Pentamidine**	Fisons Corporation Bedford, Mass. (617) 275-1000	Pneumocystis carinii pneumonia (prophylaxis)
	LyphoMed Rosemont Park, IL (312) 390-6500	Pneumocystis carinii pneumonia (treatment and prophylaxis)
	National Institute of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717	Pneumocystis carinii pneumonia (treatment and prophylaxis)
Foscarnet	Astra Pharmaceuticals Products Inc., Westboro, Ma. (508) 366-1100, ext. 2370	Cytomegaloviral retinitis
Ansamycin (in combination with other drugs).	Adria Laboratories, Dublin, Ohio (614) 764-8100	Mycobacterium avium intracellulare disease infection (an organism closely related to Mycobacterium tuberculosis)
Spiramycin	Rhone-Poulenc Inc. Monmouth Junction, N.J. (201) 297-0100	Cryptosporidiosis (a eukaryotic organism that can cause severe chronic diarrhea)
Piritrexim	Burroughs Wellcome Co. Research Triangle Park, N.C. (919) 248-3000	Pneumocystis carinii pneumonia (treatment)

-MORE-

Immune Globulin IG-IV*	Sandoz Pharmaceuticals Corp., East Hanover, N.J. (201) 386-7500, and	Treatment or prevention of various opportunistic infections
	Alpha Therapeutics, Los Angeles, Calif. (213) 227-7526	Treatment or prevention of various opportunistic infections
	Miles Inc. West Haven, Conn. (203) 937-2205	Treatment or prevention of various opportunistic infections
	National Institute of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717	Prevention of various opportunistic infections in children
	National Institute of Child Health & Human Development Bethesda, Md. (301) 496-5133	Prevention of various opportunistic infections in children
Cryptosporidiosis Immune Globulin (from specifically immunized cows' milk)*	National Institute of Allergy & Infectious Diseases, Bethesda, Md. (301) 496-5717	Cryptosporidiosis
Fluconazole	Pfizer Inc., New York, N.Y. (212) 573-2323	Esophageal candidiasis and Cryptococcal Meningitis
Nystatin	Squibb Corp. Princeton, N.J. (609) 921-4650	Prevention of oral candidiasis

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IND--EXPERIMENTAL IMMUNO-MODULATING AGENTS

EXPERIMENTAL TREATMENT	SPONSOR	INDICATION
r-Interleukin-2 analogue*	Cetus Corp. Emeryville, Calif. (415) 420-3232	Kaposi's Sarcoma
Lymphoblastoid interferon*	Burroughs Wellcome Co. Research Triangle Park, N.C. (919) 248-3000	Kaposi's Sarcoma

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-MORE-

IND--EXPERIMENTAL ANTI-NEOPLASTIC AGENTS

EXPERIMENTAL TREATMENT	SPONSOR	INDICATION
Piritrexim Isethionate	Burroughs Wellcome Co. Research Triangle Park, N.C. (919) 248-3000	Kaposi's Sarcoma
Doxorubicin (see note below)	National Institute of Allergy and Infectious Diseases, Bethesda, Md. (301) 496-5717	Kaposi's Sarcoma
Tumor Necrosis Factor*	Genentech Inc. San Francisco, Calif. (415) 266-1000	Kaposi's Sarcoma
Menogaril	National Cancer Institute Bethesda, Md. (301) 496-6641	Kaposi's Sarcoma
M-BACOD (with Retrovir)	National Institute of Allergy and Infectious Diseases, Bethesda, Md. (301) 496-5717	Primary Lymphoma

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Note: Doxorubicin is an approved commercially available anti-cancer agent. This is an experimental use of the drug.

* These products are considered biologic products. Interferon products also have anti-infective and immune-modulating properties.

** These products have been designated for Orphan Drug status under FDA's Orphan Products Development Program. This program provides tax and other financial incentives for the development of potential therapies for serious, but relatively rare diseases.

TREATMENT INDs

On Nov. 30, 1988, Treatment IND status was granted to ganciclovir -- an experimental therapy for AIDS patients with sight-threatening cytomegalovirus (CMV) retinitis, an eye infection that can lead to blindness. NIAID is

-MORE-

sponsoring this treatment IND, as well as a controlled clinical trial of the drug with Syntex Corp. of Palo Alto, Calif.

Treatment IND status allows for expanded distribution of experimental therapies for immediately life-threatening or serious conditions before marketing approval has been granted, after safety and some degree of efficacy have been demonstrated in clinical testing.

Patients with immediately sight-threatening CMV retinitis will be eligible under this treatment IND. Patients with CMV retinitis that is not threatening sight will be eligible for a controlled clinical trial of ganciclovir in which patients will receive either immediate or later therapy with very close monitoring for clinical deterioration.

Physicians and patients interested in either protocol can call the Ganciclovir Study Center at (301) 497-9888.

Trimetrexate, an experimental drug for treating Pneumocystis carinii pneumonia (PCP), in Feb. 1988, became the first AIDS-related drug to be granted treatment IND status under FDA's new regulations. The new protocol allows the treatment IND's sponsor, the National Institute of Allergy and Infectious Diseases (NIAID), to provide the experimental drug therapy to AIDS patients with PCP who experience severe or life-threatening adverse reactions to the conventional treatments using the approved drugs, injectable pentamidine and trimethoprim/sulfamethoxazole.

Since trimetrexate is toxic to bone marrow cells and the gastrointestinal tract, and potentially lethal at the dose needed to treat PCP, it must be administered with leucovorin, an approved drug which helps protect human cells from the harmful effects of drugs like trimetrexate. Even with leucovorin, careful monitoring is essential to fully ensure patient safety.

-MORE-

02. 27. 88 09:54 AM FDA

Controlled clinical studies sponsored by NIAID are now being conducted to more fully evaluate the benefits and risks of trimetrexate in larger numbers of patients.

Physicians interested in learning about the details of this distribution can contact an NIAID hotline at 1-800-537-9970 within the United States.

VACCINES:

At present, the Public Health Service has recommended certain steps that individuals can take to avoid exposure to HIV infection. Theoretically, one of the most effective ways to prevent the spread of this infectious disease would be through vaccination. However, because of the nature of the virus, scientists predict vaccines against it will take a number of years to develop. But there has already been a good deal of progress in the search for such vaccines.

On Aug. 18, 1987, FDA sanctioned the first human testing of a candidate vaccine against HIV in the United States. The vaccine is manufactured by MicroGeneSys Inc. of West Haven, Conn. A study of the vaccine is being conducted by the National Institute of Allergy and Infectious Diseases at its Clinical Center in Bethesda, Md. (301) 496-5717, and through its extramural program, which includes a network of vaccine evaluation units at medical schools across the country.

On Nov. 25, 1987, FDA granted permission for testing of a second experimental vaccine. The vaccine, produced by Bristol-Myers Co. of New York, N.Y., is made from vaccinia virus into which genes for the surface or envelope proteins from HIV have been inserted by recombinant DNA techniques.

-MORE-

In the future, FDA will continue to encourage the development of drugs and vaccines against HIV and HIV-related opportunistic infections through the Orphan Products Development Program and by cooperating with sponsors whenever possible. In addition, the agency will update this Talk Paper on a regular basis.

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Line 12

Food and Drug Administration

Submission for the Record

Hearing Before The

Committee on Labor and Human Resources
United States Senate

February 7, 1989

9/14 final agreement

AGREEMENT

Preamble

The American National Red Cross (ARC) and the Food and Drug Administration (FDA) agree to the following actions, to further ensure the safety of whole blood and blood products, as a result of the findings of recently completed and ongoing inspections of ARC regional blood services.

Terms of the Agreement

1. The ARC national headquarters will establish, through the Responsible Head, clear lines of control of the regional blood services with respect to compliance with ARC directives and federal regulations.

2. The ARC will standardize, revise, and update standard operating procedures (SOP) used by all regional blood services. No region may implement a variance to a national headquarters directive until written approval has been obtained from the office of the Responsible Head.

3. In the area of blood collection, the ARC will explore the feasibility of alternative systems to the current practice of accepting blood donations from donors temporarily deferred due to repeatably reactive screening tests for anti-HIV and HBsAg. The ARC will prepare a written proposal within 60 calendar days and submit it to the FDA.

4. The ARC will describe, in writing, and submit to the FDA within 30 calendar days, its revised audit program with respect to the qualifications of employees performing the audits; parameters of the audits; and their frequency. FDA will evaluate the ARC program and provide, as appropriate, assistance to the ARC in developing a more comprehensive audit program. The ARC will implement and formalize the FDA approved program of audits within 30 calendar days after approval.

5. Employee training programs will be initiated and documented to ensure that employees understand their duties and responsibilities for the safety of the blood supply. All employees involved in the manufacture of blood products will have undergone such training within 30 calendar days.

   In addition, SOPs for training employees with computer related job responsibilities will be developed and in place within 60 calendar days. Such training will include measures to: a) ensure data security; and b) limit access to authorized personnel only. Following development of the SOPs, staff training will begin immediately and will be completed within 90 calendar days. New staff will be trained prior to assuming their responsibilities, and all staff will be subject to periodic competency tests or reviews. Training and competency testing will be documented.

6. The ARC has conducted a comprehensive evaluation of the standard computer system (IBIS/RBIS) and will submit to FDA within 30 calendar days a ranking of problems in their order of seriousness with respect to potential impact on the blood supply, and a written protocol describing in detail the manner and time frames under which corrective action will be effected and verified.

   A plan for a similar comprehensive evaluation of vendor supplied hardware and software, and non-standard computer systems in use in regional blood centers will be submitted to FDA within 45 calendar days.

   The proposed SOPs for change procedures for standard and non-standard computer systems will be submitted to FDA within 60 calendar days.

   The ARC will not add to, or significantly change, existing hardware/software systems until all facets of the corrective action plans have been reviewed by FDA, without prior written notice to FDA of any proposed changes.

7. The ARC will establish written procedures to conduct and document periodic reviews to evaluate the integrity of ARC computer systems, to ensure that data are retrievable and accurate.

8. The FDA acknowledges ARC's commitment to the terms listed above, and this Agreement is being incorporated into The American National Red Cross license application file maintained at the Center for Biologics Evaluation and Research (CBER). The ARC further commits to submit to CBER, in the form of license application amendments, all proposed procedures and protocols undertaken to effect the terms of this Agreement.

Lewellys F. Barker — 14 Sept. 88

Lewellys F. Barker, M.D., Chief Medical Officer, American Red Cross — Date

Victor W. Schmitt — 9/14/88

Victor W. Schmitt, Vice President, Blood Services, American Red Cross — Date

S. Gerald Sandler — 9/14/88

S. Gerald Sandler, M.D., Responsible Head, U.S. License No. 190, and Associate Vice President, Blood Services, American Red Cross — Date

John M. Taylor — 9/14/88

John M. Taylor, Associate Commissioner for Regulatory Affairs, Food and Drug Administration — Date

Paul Parkman — 9/14/88

Paul D. Parkman, M.D., Director, Center for Biologics Evaluation and Research, Food and Drug Administration — Date

Thomas S. Bozzo — 9/14/88

Thomas S. Bozzo, Director, Office of Compliance, Center for Biologics Evaluation and Research, Food and Drug Administration — Date

The CHAIRMAN. I just have a couple of other areas, and I want to yield to my colleagues for questions.

With regard to DHPG, you have a reference on page 12 of your testimony, and you indicate—well, it appears that everybody including the NIH AIDS Chief says this drug works. As I understand, it has already been licensed in six other countries. And I am just wondering why it is necessary to have more trials.

Dr. YOUNG. This is a very difficult issue, Senator. The total experience with the drug was with a compassionate IND. There have been no clinical trials either against an historical basis or against a placebo control. These have been studies where the drug has been released for compassionate uses.

Unfortunately, when the data were reviewed, we did not have any evidence of the safe dose that we could be sure of or concrete evidence of effectiveness. We therefore, in collaboration with NIAID, tried to develop a treatment IND, continue the compassionate use, and develop a clinical trial.

Just in December, this clinical trial was developed and submitted with sponsorship of NIAID. I asked Dr. Fauci last week if he would bring together his AIDS treatment unit leaders and see whether they can shed any light on this. There are a lot of anecdotal testimonials, but I am afraid, Senator, if we were to go ahead with an approval now, we would not have either concrete approval for safeness or concrete approval for effectiveness. And that is what is bedeviling us. We would be making it pretty much pre-1938, and that has been a problem for us.

The CHAIRMAN. Obviously, we are committed to efficacy and safety. But we had our July hearing, and I asked with respect to DHPG, do you agree it is effective, and we got pretty much the same answer as we are getting now in February.

Dr. YOUNG. Yes; there have been no clinical trials.

The CHAIRMAN. Well, I think the point is that certainly there is extremely strong anecdotal evidence that it is effective, and it is working. We have got so few drugs in the AIDS area where we have made that much progress. And it would just appear that there is pretty uniform opinion that it is effective, and it does work. We just wonder whether this is something that is getting caught up in red tape and bureaucracy, or whether the concerns are as real as you state.

Dr. YOUNG. Senator, nothing would please me more than to have those anecdotal data converted to evidence that could be submitted. That is why I called Dr. Fauci last week, to see whether we could get these individuals in who have anecdotal data, so that we can get those presented to us.

We do have those concerns that have been raised, but as you just said, we need to have evidence of the safe dose and what is effective. This is particularly true since this drug is quite poisonous; it will reduce the white blood cells, it will cause anemia, and it may even cause the individuals not to take AZT. But I wonder—Dr. Bilstead, this is in your division of responsibilities—would you be able to comment further on that, please?

Dr. BILSTEAD. Well, the issue of the data that we have available on ganciclovir has, as Dr. Young indicated, been a very difficult one for us. The data were not from a controlled trial, and they

were data that were not collected at predetermined time points. And we looked at the data very carefully to try to determine whether we had sufficient information in order to compare the drug with some sort of historical control and be able to say that it is effective.

We found that we simply did not have the data on the historical control to be able to compare with the patients who were treated and to be able to say that it was effective. We spent hundreds of hours going over the data and in discussions and meetings with the company in order to try to find additional data that might help to support the approval.

The CHAIRMAN. Well, you know, you have Dr. Fauci, who is certainly a responsible researcher and scientist and bears important responsibility, who is quoted as saying, "To me it was a major problem. In my own personal experience, it has been very effective"—and then the other stories that have been in the papers, which I am sure you are familiar with, where you have the other doctors, talking about using this particular drug. I will include the newspaper articles as a part of the record.

[Newspaper articles follow:]

2-6-87

F.D.A. Said to Be Re-Evaluating Order for More Studies on an AIDS Drug

By GINA KOLATA

In an unusual move, the Food and Drug Administration is reconsidering a recent decision to require further studies before approving a drug used to treat a pernicious viral infection that afflicts many AIDS patients of their vision, a senior official at the agency says.

The reappraisal follows an outpouring of protest about the decision by some doctors and advocates for AIDS patients.

The drug, gancyclovir, is the only one available to treat cytomegalovirus infections that eventually afflict almost AIDS patients. The infections not only threaten the retina but also cause debilitating intestinal inflammation.

Many doctors have used gancyclovir (pronounced gan-SIKE-klo-veer) in AIDS patients for years, receiving it from the manufacturer free under F.D.A. rules that allow "compassionate use" of unproved drugs. On the basis of experience with thousands of patients, many doctors have become convinced that the drug is highly effective in preventing blindness and relieving intestinal problems.

No Guarantee of Treatment

But in December, in a decision attacked as unreasonably cautious by many doctors and patients, the F.D.A. said it would not approve sales of the drug until a new clinical trial was completed.

Under the terms of that study, which began last month, the drug is given to all patients whose infection has traveled across the eye and is about to affect the center of the retina, which is crucial for vision. But those with less advanced viral infections may be assigned either to receive the drug or to receive no treatment for purposes of comparison. New patients with the viral infection can only obtain the drug by enrolling in this study and thus facing a chance of being placed in the untreated group.

> Doctors say there is evidence that the drug prevents blindness.

A high-level official of the agency, speaking on the condition of anonymity, said on Saturday that the F.D.A. Commissioner, Dr. Frank Young, was planning to tell his staff Monday that there would be a re-evaluation of the decision to require the clinical trial. The official said the move was prompted by a telephone call last week from Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases in Bethesda, Md., who urged Dr. Young to reconsider the body of anecdotal data on gancyclovir's effectiveness.

It follows months of controversy as advocates for AIDS patients argued that the F.D.A. was in effect forcing patients to jeopardize their sight.

Reached at home yesterday, Dr. Young declined to comment.

Dr. Fauci said in a telephone interview on Saturday that he was particularly moved by the plight of patients with retinal infections.

"I was getting more and more concerned about what a difficult position" people with retinitis caused by cytomegalovirus were in, Dr. Fauci said. "To me, it was a major problem." He added, "In my own personal experience," gancyclovir has been effective.

The F.D.A. official said Dr. Young planned to meet with Dr. Fauci and other scientists within three weeks to discuss what many doctors see as an accumulating body of compelling evidence that the drug works, the F.D.A. official said.

When the manufacturer, Syntex Corporation of Palo Alto Calif., applied to the drug agency for approval to market gancyclovir, it had no data from a scientific study. Instead, it had only clinical experience from doctors using it under the compassion rule. The F.D.A. historically has rejected such anecdotal evidence, asking instead for evidence from clinical trials in which some patients are given a drug and others not.

The agency rejected Syntex's application, saying more data were needed on its safety and efficacy. After extensive talks with F.D.A. officials, Syntex announced last December that it would start a clinical trial.

The drug is no longer available to new patients unless they enter the study, which must be arranged through a doctor at a major medical center. Since the drug is not on the market its cost has not been set, but nursing care for the daily intravenous administrations can be costly and some insurance plans will not cover that cost.

Even if gancyclovir does work against cytomegalovirus, it is not a panacea. It must be given intravenously every day for the rest of the patient's life or the virus will recur.

In addition, it can suppress white blood cells, and some patients cannot tolerate both gancyclovir and azidothymidine, or AZT, the only drug shown to prolong the lives of AIDS patients. Some patients have been forced to choose between taking a drug that may save their sight or one that may prolong their lives. Most have chosen gancyclovir, doctors say.

One reason some experts say a controlled experiment is needed is that doctors are unsure how soon to put patients with cytomegalovirus on gancyclovir, given its potential dangers.

Dr. Fauci called Dr. Young last Wednesday after a meeting with several representatives of the AIDS Coalition To Unleash Power, a group of advocates for AIDS patients, more commonly known by the acronym ACT UP and because of its involvement in numerous demonstrations. On Friday evening, Dr. Fauci called Bill Monaghan, a member of ACT UP, and told him that Dr. Young had agreed to meet with Dr. Fauci and other researchers to look again at gancyclovir data.

A Doctor's Experience

"I don't think you'll find a single physician who treats AIDS patients who doubts gancyclovir's safety and efficacy," said Dr. Daniel C. William, a New York internist with a large AIDS practice. Dr. William added that gancyclovir had transformed the meaning of cytomegalovirus infections.

"In the pre-gancyclovir era," he said, AIDS patients with the retinitis became blind. "It was a very predictable, rapidly progressing disease." With gancyclovir, he said, his patients keep their sight.

And previously, patients with cytomegalovirus gastritis were in great pain, lost alarming amounts of weight and were malnourished because they could not eat, Dr. William said. With gancyclovir, "you give them the drug and their pain goes away and they eat again," he said. "It's a very obvious cause and effect."

The new clinical trial required by the F.D.A. was designed by Dr. Fauci's institute. In the study, patients whose retinitis had not yet progressed to a point at which it directly threatened their sight would be randomly assigned to receive either gancyclovir or no treatment. The patients would be monitored and those receiving no treatment would be given the drug as soon as their vision was directly threatened.

Describing the study as "mean," Dr. William noted that the virus infection can proceed at an erractic and unpredictable pace, so that some patients could lose some of their sight before their infection could be officially classified as sight-threatening, thus qualifying them for the drug in the study.

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San Francisco Chronicle Feb 2, 1989

SPECIAL REPORT

AIDS Drug Approval System Under Attack

By Randy Shilts
Chronicle National Correspondent

Bethesda, Md.

From week to week, Tim Elliott watches the field of vision in his left eye grow smaller, as if big jaws are chomping a larger and larger crescent out of his eyesight.

He is going blind.

The medication that works for most people suffering from AIDS-related blindness, a drug called DHPG, does not work well for him. There is another drug, Foscarnet, that has a 90 percent chance of working.

But Elliott can't get it.

The drug's maker, Astra Pharmaceutical Products, will not let anybody who has used DHPG take Foscarnet.

If Astra gave its drug to people who have tried DHPG, the Food and Drug Administration might not accept the studies showing that Foscarnet works. Then Foscarnet would not be licensed, and Astra would lose lots of money.

It is not scientifically reasonable to exclude past DHPG users from using Foscarnet. Scientific evidence shows that the body eliminates the drug within 24 hours, according to DHPG's manufacturer.

But what is reasonable apparently does not matter. What matters is what the FDA wants, and what the FDA wants is "clean data."

Elliot may not be able to provide clean data because he has used DHPG. So from week to

Last in a series

week, his field of vision grows smaller and smaller.

"I'm going blind," said Elliott, 40, a former systems analyst with the state government. "And the FDA is playing bureaucratic games."

Welcome to the world of drug regulation.

It is a world over which the FDA, known as "the agency" to the pharmaceutical industry, is lord and master. Normal standards of common sense do not always apply, because the FDA sets all the rules and makes all

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AIDS Treatments Held Up

From Page 1

the decisions — and there is no appeal.

It is to the FDA that all proposed AIDS treatments — as with drugs for any disease — must go after they have navigated the complicated process of discovery, development and clinical trials.

Not surprisingly, there have been problems.

Unfair Criticism

More than any other arm of the federal government, the FDA has found itself taking the heat from AIDS advocacy groups frustrated by the dearth of AIDS treatments. Three months ago, 176 demonstrators were arrested during a rowdy protest at the FDA office building in Bethesda, Md.

Top FDA officials argue, with some justification, that they are the whipping boys for people angry at problems in which the FDA played no role.

The lack of AIDS drugs stems largely from long delays of NIH clinical trials, as well as the slow start of the drug discovery process within the pharmaceutical industry. The FDA notes that it has been given relatively few drugs for AIDS to approve or disapprove.

"There's this fantasy that there are all these drugs at the FDA and all you have to do is get a mechanism and they would be released," said Dr. Frank Young, FDA commissioner since 1984. "There's no backlog of drugs at the FDA. No procedure can make drugs out of whole cloth."

This is true.

What is also true, however, is that in instances where the FDA has become involved with AIDS drugs, accusations of bureaucratic intransigence have been quick to follow.

Many AIDS researchers, as well as AIDS advocacy groups, charge the FDA with an array of transgressions that, they say, are impeding the effort to get AIDS remedies.

"In a crisis situation, the FDA has been very slow to change," said Dr. Jere Goyan, who served as FDA commissioner during the Carter administration.

Goyan, dean of the School of Pharmacy at the University of California at San Francisco, recently stunned the medical establishment by writing in the Journal of the American Medical Association that the FDA's policies are out of step with the harsh realities of the AIDS epidemic.

"When the American people have a concern, you just don't say they're too stupid to understand and they need to listen to us (the FDA)," he said. "We may need separate policies for this particular epidemic."

Blinded By Bureaucracy

No single aspect of the AIDS epidemic has better illustrated the controversy over the FDA than the new treatments for blindness caused by the herpes virus cytomegalovirus, or CMV. About 5 percent of AIDS patients contract retinitis, caused by CMV run wild in the eye. But clinicians fear that number is growing because AZT, a drug that extends the lives of AIDS patients, is allowing patients to live long enough to contract these more exotic diseases.

In 1985, researchers in early studies noted that the drug DHPG was extremely effective in curing CMV retinitis.

Normally, the drug company that owns a drug's patent would prove this effectiveness to the FDA by running a clinical trial in which some patients are given DHPG while others are given an inert substance, or placebo. The response of the untreated placebo group could then be used as a control against which the effect of the drug could be measured.

Placebo-controlled studies are what the FDA traditionally has demanded as proof of a drug's efficacy. No other type of study can prove as quickly and definitively whether a drug works, experts agree. Such studies produce "clean data," results that cannot be tainted by the bias of a researcher or drug company.

The company that owns the DHPG patent, Syntex Pharmaceuticals, however, did not launch such studies. The Palo Alto-based firm will not say why, because it refuses comment on the DHPG controversy.

John James, editor of AIDS Treatment News, suggests that it was because the company was fighting for the patent to DHPG with another company, Burroughs-Wellcome. Syntex, James said, may not have wanted to start expensive trials when it was not clear at the time that they would end up owning the drug.

DHPG, however, came into wide use because Syntex got permission from the FDA to release the drug under a "compassionate-use protocol," in which a company is allowed to release a drug for a serious illness as long as the firm does not charge for it.

The experience of treating more than 3,600 patients under the compassionate-use protocol has led AIDS researchers to universally accept one truth about DHPG — it works.

AIDS advocates recently held a Hospital to protest the difficulty

"I don't think you'll find any clinician anywhere who has used this drug who does not believe it has biological activity," said Dr. Bruce Polsky, a CMV specialist and AIDS researcher at Memorial Sloan-Kettering Cancer Center in New York City.

"It's unusual when you have a patient going blind when you can give them a drug and turn it around," he said.

Dr. John Mills, chief of infectious diseases at San Francisco General Hospital, says he believes in DHPG "to a theological certainty."

Everybody believes in DHPG.

But the FDA won't license the drug.

After settling its patent suit with Burroughs-Wellcome, Syntex took the records of the patients treated by DHPG under the compas-

) by 'Bureaucratic Games'

BY LIZ HAFALIA/THE CHRONICLE

**sit-in at San Francisco General
f getting the drug Foscarnet**

BY JEFFREY MARKOWITZ/SPECIAL TO THE CHRONICLE

Dr. Ellen Cooper oversees FDA approval of AIDS drugs

sionate-use protocol and attempted to use them as the evidence needed to secure licensure.

The FDA said no.

"The problem with DHPG was that control data — or data on control efficacy — was not presented," said Dr. Ellen Cooper, who oversees FDA approval of AIDS drugs as director of the Division of Antiviral Drug Products.

"The problem was that doctors were using it as part of a compassionate-use (program)," she said, instead of a placebo-controlled study.

The FDA blames Syntex for not presenting the clean data that a placebo-control study can provide. Says one Sloan-Kettering researcher bitterly, "The FDA wants a double-blinded study in which people literally go blind."

After eight months of stalemate, the FDA, Syntex and National Institute of Allergy and Infectious Diseases, or NIAID, came up with a compromise in which patients with CMV on the periphery of their retina will be placed at random into treatment and placebo groups.

Those who do not receive treatment will be regularly monitored. If the CMV appears to be advancing from the periphery to the center of the retina — where the lesions actually threaten sight — the patient will be dropped by the study and allowed access to the drug. In announcing the compromise, the FDA said it was an example of how flexible it is willing to be.

Most doctors consider the study a waste of time, because it will prove a scientific point that they already know. Other doctors go as far as to say they cannot ethically participate in such a study.

"I think it's teetering right on the edge of what's ethically acceptable in 1989," said Polsky, a researcher with the NIAID clinical-trials program at Sloan-Kettering. "With any infection that threatens a major organ such as the eye, you want to treat earlier rather than later."

Chilling Effect

Syntex's problems in licensing DHPG have had a chilling effect on the pharmaceutical business. "Compassionate use" has become a major industry cuss word.

Few pharmaceutical companies want to be left treating thousands of patients for no charge, as Syntex is, when the results of that treatment cannot be used for licensing.

Astra will not release its Foscarnet on a "compassionate-use" protocol and is instead allowing only 59 patients in the country to use the drug as part of the FDA-approved study.

Patients such as Elliott do not qualify for the Foscarnet study because no patient who has ever used DHPG is allowed to participate. Although Syntex says DHPG is easily metabolized and disappears from the body within 12 to 24 hours, the use of such patients still may taint the "clean data" that the FDA prefers.

There is an even more tragic twist. Study restrictions are forcing many AIDS patients to choose between preserving their sight or preserving their life.

Because DHPG harms the ability of bone marrow to produce blood cells, patients cannot take both DHPG and AZT, which has the same side-effect. This has left many to make the awful choice between whether to use DHPG to save their sight or use AZT to extend their life.

If these patients had access to Foscarnet, which does not suppress bone marrow, they would be spared the grisly dilemma.

He Gave Up AZT

Terry Sutton, a 33-year-old school teacher, made the choice between sight or life — he gave up AZT so he could use DHPG and still see.

"I could live longer if I could take Foscarnet and still get my AZT," said Sutton, who taught emotionally disabled children in San Francisco. "Now I'll be able to watch my death scene. If it weren't for the FDA, I'd be able to have a shot at life."

FDA Commissioner Young says he is "saddened" by the dilemma faced by people like Elliott and Sutton, but he stands firm on the need for traditional placebo-controlled studies.

"That's where we tried to do something nice (in allowing the compassionate-use protocol) and we did it wrong," he said.

Without data from the NIAID study now under way, however, Young says the agency does not have "the data we need to know whether this really works. We can't accept testimonials."

Agency officials note that without more exacting studies, they will not be able to tell doctors at what stage of the disease DHPG should be administered to patients and what its long-term side effects may be.

Because of such issues, some scientists back the FDA.

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'Games' The FDA Plays

From Page A8

"I can have sympathy for the role the FDA has taken," said Dr. Paul Volberding of San Francisco General Hospital's AIDS Clinic.

Some researchers argue that the agency needs to hold firm, so that it does not set a precedent that would allow other, less-effective drugs to gain licensure on the basis of endorsements from researchers.

Aerosol Drug

Nevertheless, breaches are beginning to appear in the FDA approval process.

Yesterday, an FDA spokesman confirmed that the agency will soon announce that it will allow the release of an aerosol version of the antibiotic pentamidine, which has been found to prevent Pneumocystis carinii pneumonia, the virulent illness that strikes AIDS patients.

Before yesterday, however, the agency had maintained that it could not approve the drug, in part because researchers have been reluctant to conduct placebo-controlled studies.

FDA critics said the decision to allow the release of pentamidine was long overdue, because the drug has been in wide use on an underground basis at hundreds of medical offices around the country. Still, researchers said the move represents a radical departure from traditional FDA criteria.

"The term we're hearing out of Washington now is 'sliding scale' — that they're going to start weighing in the seriousness of the situation before applying their old tried-and-true standards," said one researcher involved in pentamidine studies, who asked not to be named.

"This is the start of a whole new day," he said.

Pressures are mounting on the FDA from a number of directions.

The National Cancer Institute's new director, Dr. Sam Broder, recently presented a report to a panel reviewing FDA rules on cancer and AIDS treatments that accused the FDA of being "mired in a 1960s philosophy." The report said the agency has not kept up with progress being made in technologies that fight AIDS and cancer.

Given the credibility of such critics and the sheer weight of political pressure, it is expected that the FDA drug-approval system as it now stands will not be intact much longer — at least as it affects drugs for life-threatening diseases such as cancer and AIDS.

Government deregulation has been a pet project of President Bush. As vice president, he persuaded the National Cancer Advisory Board to empanel a committee that is now reviewing procedures for the release of AIDS and cancer drugs.

For the people awaiting AIDS treatments, the machinations of official panels, government regulators and even scientists in their drug-discovery labs seem hopelessly abstract — at least when juxtaposed with the immediacy of the deadly disease and the remedies that are promised but never seem to arrive.

"I keep hearing about the breakthroughs, the treatments that are coming," said Sutton, whose ailment was diagnosed as AIDS five months ago. "I think I might have a shot if I can hold out long enough to be here when they come. If they come. But what is it that keeps them from me?"

Pausing, he added, "My life depends on it."

BY ERIC LUSE/THE CHRONICLE

Tim Elliott is going blind because of AIDS but cannot get a promising drug because of FDA procedures

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...e Chronicle ★★★★ A9

FDA Says Public Is Ignoring Its Positive Steps in AIDS Fight

By Randy Shilts
Chronicle National Correspondent

Bethesda, Md.

FDA officials say the agency's aggressive response to the AIDS epidemic is being overlooked amid the chorus of critics demanding the speedier release of drugs.

Dr. Frank Young, commissioner of the Food and Drug Administration, says that a series of new initiatives and a streamlined system of paperwork for AIDS treatments have reduced by half the 10 years it normally takes to get a new drug approved.

"We have felt the urgency of this," said Young.

To make sure that studies on AIDS drugs get top priority for review, for example, Young has rated all AIDS drug trials "I-AA," meaning that they have to move in and out of FDA offices within days of submission.

Speed of Light

The first drug to enjoy expedited FDA approval was AZT — its license was reviewed and approved in 107 days in 1987. By bureaucratic standards, this was the speed of light.

"It took a lot of internal agony to change the system," said Young, who has served as FDA chief longer than any commissioner in a generation. "The highest goal was expediting drug-review process."

Although often critical of the FDA, pharmaceutical industry representatives have applauded the agency for meeting with company researchers early in the drug development process to discuss what studies are needed for approval.

"If you communicate with the agency and find out what they need, you can cut a lot of time out of the process," said Dannie King of O'Claussen Pharmaceuticals in Corte Madera. "They're more than happy to meet with people and speed things up."

FDA defenders note that the ... the end of increasing load of approvals and drug applications with a small staff. The presidential AIDS commission last year recommended substantial increases in staff and funds to help handle the load.

"I can't solve it with smoke and mirrors," said Young.

Some Changes

Reviews have been mixed, however, on the two major changes in FDA procedure that have been put into effect during the AIDS crisis to speed the release of drugs for life-threatening diseases.

The first came in the dramatic 1987 announcement of the Treatment IND, or investigational new drug, program that would speed treatments to patients with life-threatening diseases before the drugs were approved. The imminent release of aerbsol pentamidine, announced by the FDA yesterday, will be made under the provisions of the Treatment IND.

As originally proposed by Young, the Treatment IND program would have allowed the release of drugs that "may be efficacious" to treat AIDS patients. As applied, however, the program is now a channel through which drugs that have met the agency's tough efficacy standards can be released before paperwork is completed for licensure as an approved substance.

The release of a drug under the Treatment IND comes with conditions that have severely restricted its use.

For example, no company is allowed to profit by the release of the drug before licensure. Therefore, drug firms must prove to the FDA that any charges for the drug are strictly to recoup the cost of making it.

Drug firms are loath to open their books to anyone, and few rushed to get Treatment IND's for AIDS drugs. In fact, the FDA says only six have applied. Of these, only two were approved, and these approvals came with tight restrictions.

One of the approved drugs was trimetrexate, which was found to be effective in treating Pneumocystis carinii pneumonia, the most common AIDS-related disease. When approving a Treatment IND for trimetrexate last February, however, the FDA said the drug could only be used when there was an "adverse reaction" to the two approved Pneumocystis drugs.

The problem with the restriction was that some Pneumocystis sufferers did not respond to those two drugs — but did not suffer adverse reactions to them. They could be dying and trimetrexate could save them, but the FDA would not allow use of the drug because the required adverse reactions did not occur.

It took six months of congressional pressure and the threat of a lawsuit to get the FDA to change the rule.

Although Young considers the Treatment IND program to be a success, most researchers agree with former President Reagan's AIDS commission, which pronounced the initiative a failure.

"The FDA is great at PR gestures," said Jay Lipner, an attorney who advises several AIDS organizations on FDA policy. "There's always less to them than what meets the eye."

Bush Initiative

Three months ago, amid much fanfare, Young announced a second program to speed the release of AIDS and cancer drugs. Because it was devised in consultation with advisers to the then-vice president, the new program was called the Bush Initiative.

Under its provisions, drugs could win licensure once they passed a second phase of testing — skipping a currently required third stage of testing — provided companies continued to monitor the compounds after they were marketed.

The proposals, however, only allow the FDA to speed approval. They do not require swifter action. The program has not yet been implemented, so its effect on speeding the release of drugs cannot be determined.

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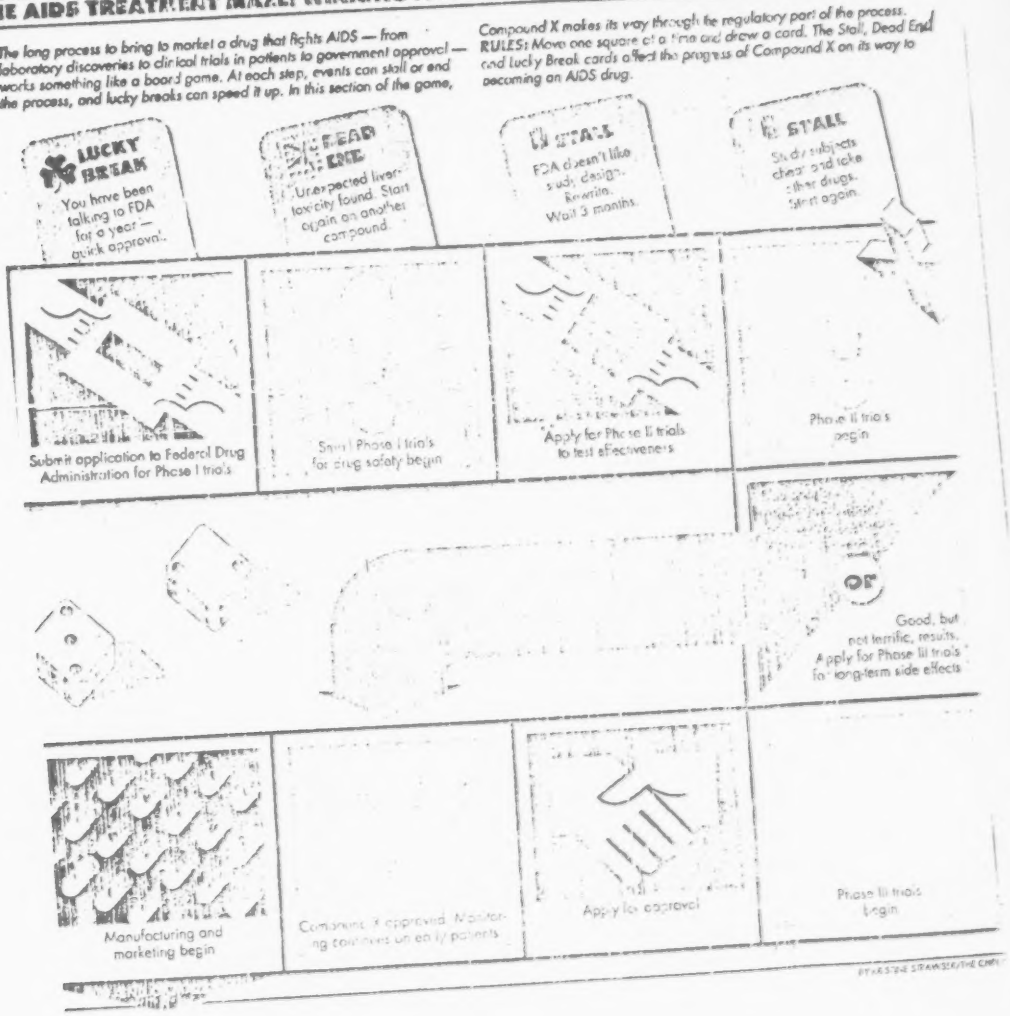
THE AIDS TREATMENT MAZE: WINNING FDA APPROVAL FOR A DRUG

The long process to bring to market a drug that fights AIDS — from laboratory discoveries to clinical trials in patients to government approval — works something like a board game. At each step, events can stall or end the process, and lucky breaks can speed it up. In this section of the game, Compound X makes its way through the regulatory part of the process.

RULES: Move one square at a time and draw a card. The Stall, Dead End and Lucky Break cards affect the progress of Compound X on its way to becoming an AIDS drug.


LUCKY BREAK
You have been talking to FDA for a year — quick approval.
DEAD END
Unexpected liver toxicity found. Start again on another compound.
STALL
FDA doesn't like study design. Rewrite. Wait 3 months.
STALL
Study subjects cheat and take other drugs. Start again.
Submit application to Federal Drug Administration for Phase I trials
Start Phase I trials for drug safety begin
Apply for Phase II trials to test effectiveness
Phase II trials begin
OR
Good, but not terrific, results. Apply for Phase III trials for long-term side effects
Manufacturing and marketing begin
Company X approved. Monitoring continues on early patients
Apply for approval
Phase III trials begin

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Justice Gone Blind:
CMV Patients Fight for Their Sight

BY TIM KINGSTON

Tim Elliot is in a race to save his sight from CMV retinitis, a blinding AIDS-related viral infection. But right now he is slowly losing the race — not because prospective treatments don't exist, but because of a dismaying brew of drug toxicity, Food and Drug Administration (FDA) regulations, National Institutes of Health (NIH) protocol restrictions, and what many suspect is the pharmaceutical and insurance industries' reluctance to shoulder the financial burden of distributing free experimental treatments.

Two treatments exist for CMV retinitis — ganciclovir and foscarnet; neither drug is FDA approved, though both are in clinical trials. Both have serious suspected and known side effects, but, if left untreated, the virus virtually guarantees blindness.

"I want access to foscarnet and I want access to foscarnet now," demands Elliot. He is on ganciclovir, but the drug is no longer effective. "I am doing a balancing act unsuccessfully; I am continuing to lose vision and I am on the maximum ganciclovir dosage that I can physically handle. I want to go on foscarnet so I don't go blind."

"I have been forced into making a choice between my sight and my life," blazes Terry Sutton, diagnosed with CMV in August. Sutton wants to use foscarnet so he can take AZT to treat his HIV infection. He is taking ganciclovir, but is unable to take AZT as well, because the combination severely depresses his white blood cell count. "What we are treating is CMV. What I am going to die from is HIV. I can't treat my HIV because ganciclovir plus AZT would kill me. What is the good of saving my sight, and I die in six months?"

Neither Sutton nor Elliot are eligible for current foscarnet trials because patients treated with ganciclovir are not allowed into the limited foscarnet trials now in operation. A total of 60 people are in these trials across the country, 29 of them in San Francisco.

While it is generally accepted that about 85 percent of those treated with ganciclovir respond at first, many later fail the drug, due to its serious bone marrow toxicity, which forces patients like Elliot to diminish their dosage or quit the drug altogether. They want to try foscarnet because there is no alternative drug. Others like Sutton want to try and treat their HIV infection with AZT, which is impossible when using ganciclovir.

Foscarnet is looked at as an *alternate* treatment. It has been tested on a compassionate basis on 500 CMV patients in Europe and Canada. Alf Larsson of Astra, the Swedish manufacturer of foscarnet, said there is a good clinical response in some 80 to 90 percent of the cases. He warned, however, "This data is uncontrolled compassionate use data; this may be in conjunction with other drugs." Other tests indicate that drug's effectiveness is comparable to ganciclovir, while it also has some anti-viral HIV activities. The treatment halts the growth of the CMV lesions on the retina that cause blindness, but has caused severe kidney failure in an unknown number of patients.

Foscarnet's primary advantage over ganciclovir is in its lack of bone marrow toxicity, a factor Dr. Judith Rubin, clinical coordinator and associate investigator of the National Eye Institute foscarnet study, says leads her to favor the drug over ganciclovir. The budding consensus is Foscarnet will probably prove as effective as ganciclovir. That is the case in Europe, where foscarnet is available on compassionate use. In some countries Foscarnet is the drug of choice, in others it is ganciclovir.

The struggle to get foscarnet is only the latest battle over what people with AIDS, physicians, and patient advocates see as the unethical and life-threatening denial of drugs to patients. But this conflict may finally clear the bureaucratic logjam barring access to promising AIDS treatments.

For the first time the medical establishment is listening to PWA demands for early treatment access. Dr. Anthony Fauci, head of the AIDS program and director of the National Institute of Allergies and Infectious Diseases told *Coming Up!* he will personally push the issue of foscarnet access forward at the NIH and the FDA. "Barring any unforeseen delays" Fauci says two foscarnet protocols will be approved by the FDA in early February, including a "salvage" trial aimed at people who have failed ganciclovir treatment, but are ineligible for current foscarnet protocols now.

In a surprisingly supportive statement, Fauci emphasized how — in life-threatening diseases — "We must seriously relook at how we handle the availability of drugs — while they are on clinical trial — to people who can't be on the clinical trial." Fauci carefully acknowledged the FDA's regulatory authority and praised the agency, but argued "(We) must not say, well traditionally this is the way we have done it,... let's sit down and look at it, and say, well maybe we need to do some rethinking."

He said he favors expanding access to drugs that have not been "looked at as carefully as we would have liked" — if the patients are willing to take the risk.

After meeting with patients' advocates here recently, Fauci, with some reservations, said that he is willing to make compassionate use a part of normal protocol design. "If a drug is put into a protocol at the same time there is liberal compassionate use that *won't* interfere with people going into the protocol. (I think) that as many people would go onto the protocol as if the drug were not available on compassionate use."

Sandra Kweder MD, an FDA medical officer specializing in foscarnet and ganciclovir, disagrees with granting greater access to promising but unapproved treatments. "In saying that people should have access to these drugs you are making an assumption that the drug works, *that* (assumption)... really cannot be made until the trials are conducted."

Kweder said the FDA needs more data to be convinced of these drugs' efficacy. She says, "The patient can't make an informed decision until we have more information... even at this point a clinician cannot make an informed decision because not enough is known about the drug." Kweder stressed safety is paramount, despite the dire effects of not treating CMV.

"Perhaps we (the FDA) are a little bit more protective than people would like us to be," stated Kweder. She said part of the problem is "we see a lot of the toxicities; we may have a different perspective because we hear about every case where a drug is harmful to patients."

Photo by Rick Gerharter

Terry Sutton's eyesight continues to fail as he waits for the bureaucracy to change so he can take foscarnet. For Howard Kahn (right), release of the drug will come too late. He lost his vision five months ago.

Photo by Rick Gerharter

"We must seriously relook at how we handle the avilability of drugs.... to people who can't be on the clinical trial."

—Dr. Anthony Fauci, Director
National Institute for Allergies and Infectious Diseases

According to Martin Delaney of Project Inform, Faucis and Kweder's comments reflect "the growing gap between the NIH and the FDA over these matters. They are increasingly at each other's throats."

Meanwhile, efforts are being made to push foscarnet forward in the legislature. Both Representatives Nancy Pelosi and Barbara Boxers are applying pressure to speed up the approval process for treatment IND's overall by using foscarnet as a battering ram. (A treatment IND — investigational new drug — is distribution of a drug at physician's request, with detailed data collection and at a fee, if any, determined by the company.)

Pelosi's office has been making phone calls to the NIH and the FDA to apply pressure so that the foscarnet protocols now in the pipeline will be speedily approved.

Dr. Steve Morin, Pelosi special assistant on health affairs, is working to invoke a rider to last year's Waxman AIDS bill which creates a review panel in the NIH to recommend promising drugs to the FDA for treatment IND approval. The Department of Health and Human Services then must step in to encourage the company manufacturing the recommended product to apply for a treatment IND. If the company refuses, other groups such as the Community Research Alliance can take up the option of applying for a treatment IND with FDA assistance.

Morin says that NIH panel is now gathering all available data on foscarnet to make a recommendation as soon as possible. Although the legislative effort looks promising, success will depend on how willing the FDA is to listen to the advisory panel, because the FDA retains ultimate authority over drug approval decisions.

Treatment Access and the Salvage Protocol: How Soon?

Sutton and Elliot are only two of the hun-

dreds of CMV patients who want immediate access to foscarnet, but they are not eligible for any of the trials now running because they were treated with ganciclovir. Those protocols, and many others, are presently governed by the pure subject rule, e.g. a trial enrollee can have taken no other treatment for their condition to ensure that any reactions to treatment come exclusively from the drug being tested.

"The idea of clean data terrifies me," says Sutton, "because it punishes people for trying to treat early. My roommate... has made the decision not to treat early because of the pure subject rule. What he says is 'I want to be a pure subject so that I can get access to the best protocol once it starts to move.' You only get to be a pure subject once."

That is why PWAs and patient advocates are demanding access to foscarnet — and ganciclovir — through a "salvage protocol" specifically tailored to those not eligible for the FDA approval trials; or on a compassionate use basis where the drug is distributed free by the company with limited data collection; or on a treatment IND.

Fauci told *Coming Up!* he hoped treatment IND approval for foscarnet would be pushed through the NIH in a couple of weeks to a month, and he hopes it will then be approved by the FDA in a matter of weeks. But Cheryl Karol, associate director of clinical research for the U.S. subsidiary of Astra, told *Coming Up!* the company doesn't expect a treatment IND for nine to twelve months. She also confirmed Astra does not intend to release the drug on a compassionate use basis.

That leaves the multi-center NIH-Astra funded and operated "salvage" protocol. Dr. Mark Jacobson, co-primary investigator at San Francisco General Hospital, is hopeful recruitment will begin in March, but other observers caution the trial may not be ready until April or June.

Karol says the March study is "strictly for people who have taken ganciclovir who had a toxicity problem or it didn't work." The salvage trial will allow anyone to enter who has failed ganciclovir and will include two wings of differing dosages with no placebo. Both Karol and Dr. Jacobson intimated the salvage trial will include approximately 200-250 individuals.

But, because CMV affects between 5 and 10 percent of people with AIDS, there are many more than 200 potential participants. Dr. Robert Neger, the first physician to perscribe ganciclovir for CMV retinitis, charges that "200 people is not a realistic protocol. At least 5,000 people have been treated with ganciclovir and the numbers are increasing because people are surviving longer. The numbers should be in the thousands." Karol said that if the protocol is filled, Astra is willing to expand it.

The salvage trial still excludes those now on ganciclovir who want foscarnet so they can take AZT therapy. When Terry Sutton asked Dr. Jacobson, about participating in the trial, he was told he would have to fail ganciclovir first. Jacobson said the trial simply could not include everyone who wants foscarnet. Thus a whole group of individuals who may wish to transfer from ganciclovir to foscarnet will be excluded.

Blame Enough for All

While everyone is busy blaming the FDA for lack of access to foscarnet and ganciclovir, the convoluted history of both drugs and the imperatives of the pharmaceutical market place doubtless play an equally effective role in denying drugs to those with CMV retinitis.

When Syntex corporation applied for its first compassionate use distribution for ganciclovir in May of 1984 and sent Dr. Neger the first dose of the drug, nobody could have guessed the company would wind up $25 million in the hole, for distributing the drug to over 5,000 CMV patients, and not recieve drug approval, despite the fact most doctors in the field are convinced of ganciclovir's efficacy.

According to most of the doctors and patients contacted by *Coming Up!*, Syntex is one of the few companies which has acted ethically in the content of the AIDS epidemic. Dr. Donald Kotler, an independent AIDS treatment investigator in New York commented, "(Syntex) had good results early on. People who clearly were destined to go blind had remissions, and for that reason (Syntex) felt hard pressed to change their protocol" from availability based on compassionate use to the double blind, placebo-controlled protocol, which might have resulted in worsening retinitis for trial participants.

As the numbers of reported CMV cases rose, so did the distribution of ganciclovir. In February of 1985, 100 patients were given the drug; in December 1986 almost one thousand compassionate use cases were recorded. By October 1987, over six thousand people with CMV retinitis were being treated with the drug.

Linda Thomas, media relations officer for Syntex, noted proudly, "Our position is we feel very positive about the treatment IND. No patient has been denied access to the drug." Thomas suggested that the drug's distribution "took on a life on it's own" as news of ganciclovir's success spread by word of mouth. Syntex, may however have had an additional motive for continuing compassionate use distribution, even as the cost of the distribution soared.

Syntex was in the midst of a patent battle with Burroughs Wellcome over the ownership of ganciclovir for a good portion of the time compassionate use was in effect. Burroughs Wellcome also distributed the drug to some one thousand CMV patients while the patent was in dispute. The dispute was resolved in favor of Syntex in March 1987.

It would not be unreasonable for a drug company to be reluctant to pay for full clinical trials if it is not absolutely certain it will have control over the product. It is quite likely Burroughs and Syntex were hedging their bets by distributing the drug on the much cheaper compassionate use basis and collecting data that way. Dr. Fauci told *Coming Up!* the NIH wanted Syntex to initiate clinical trials several years ago but, Syntex declined the request. Thomas described such analyses as "speculation," but acknowledged the settlement with Burroughs.

In December 1986, relying on data collected by on a thousand patients, Syntex applied for an orphan drug application for ganciclovir that would allow the company to market the drug at a self determined price for seven years. The application was denied in October 1987. Dr. Kweder said, "The bottom line is that basically adequate trials were not conducted... it was given out on compassionate usage to patients with very poor data collected... the information was never able to establish the drug really does work in a manner that outweighs the significant safety risks of the drug."

The FDA decision was heavily influenced by the recommendations of an advisory committee to the FDA made up of eleven physicians, academics and optomologists. The vote was 9-2 against granting orphan drug status, with the only dissenting votes coming from the eye specialists on the committee. Doctors familiar with the decision say the committee did not dispute Syntex's assertion that 85 percent of those treated showed remission and only 5 percent of those not treated improved. Instead the committee argued that quality and detail of the data submitted was insufficient.

The FDA decision was greeted with dismay and outrage by the medical community, even though many acknowledged Syntex's data was less that perfect. Thomas preferred to make no comment on the FDA decision aside from saying, "The real issue for Syntex now is how do we satisfy the FDA and not jeopardize the sight of patients."

Terry Sutton, however, suggests Syntex was turned down for political reasons, not just insufficient data. More than one individual contacted by *Coming Up!* argued the FDA was afraid Syntex was trying to do an end run around the regulatory process. The hypothesis is the FDA suspected Syntex was trying to get approval on a fait accompli basis using data collected in compassionate use trials without ever attempting to run detailed clinical trails.

If Syntex obtained approval on that basis, a precedent would be set that could drive an M-1 tank at 80 mph through the entire FDA regulatory system using compassionate usage as the fuel. Dr. Kweder denies the decision was designed to discipline Syntex and called the allegation a common although understandable "misconception." She argues the FDA is not

opposed to compassionate use release of drugs. Dr. Kweder noted, "I think that other drug companies are re-evaluating their own unique situation" in relation to compassionate use.

"What has happened is that (drug companies) have become very gun shy of using the compassionate use provision," says Morin. "What that means from the consumer perspective is ...that it is harder to get certain drugs. What the drug companies are of course trying to do is increase the motivation of people who participate in the kinds of basic trails that will lead to licensing." A less pleasant way of putting it is that without compassionate use, anyone wanting an experimental treatment will be forced to join a clinical trial.

The clinical trials set up by Syntex to obtain the data the FDA want are a case in point. CMV retinitis patients are having to go back on protocols that are a modified placebo control trials. Patients with sight-threatening retinitis are given ganciclovir immediately. However, those with what is called nonsight-threatening retinitis are randomized into drug and placebo groups until their retinitis either

(continued on page 11)

access to foscarnet, but they are not eligible for any of the trials now running because they were treated with ganciclovir. Those protocols, and many others, are presently governed by the pure subject rule, e.g. a trial enrollee can have taken no other treatment for their condition to ensure that any reactions to treatment come exclusively from the drug being tested.

"The idea of clean data terrifies me," says Sutton, "because it punishes people for trying to treat early. My roommate... has made the decision not to treat early because of the pure subject rule. What he says is 'I want to be a

CMV....

(continued from page 5)

becomes sight-threatening or grows. They are then allowed to have ganciclovir.

Sutton is dismayed by the prospect of another placebo trial of any sort and disputes the terms sight-threatening and non-sight-threatening retinitis. He compares the disease to bread mold: "If there is mold on your bread, it is not linear. It can pop up anywhere!" Doctors agree that retinitis could appear suddenly, but argue with close supervision such developments could be caught prior to sight loss.

Although Delaney praised the delayed placebo trial as a valid and clever solution to Syntex's protocol dilemma, that does not mitigate his critique. "I don't believe, in this country, with it's long devotion to personal liberty, that you can force people to participate in these experiments. That sounds like something Dr. Mengele would have done."

Delaney says the ganciclovir trials are a step backwards for patients' rights and access. "Ethically it takes away the patient's freedom of choice. It doesn't let the patient or the treating physician into the decision."

Even Fauci acknowledges the justification and relevance of the current ganciclovir study are "debatable" and that "there is a lot of discussion of the issue." He says that with some six thousand patients receiving the drug and a growing conviction of it's efficacy, the situation is so "clouded" that a full study may simply not be possible. Fauci says, "Perhaps the drug should be licensed now on the basis of the data we already have."

The Flowers of Syntax

Astra, foscarnet's manufacturer, contends the debacle at Syntex had no effect on the company's lack of inclination to apply for compassionate use distribution. Astra officials say they will apply for a treatment IND when safety issues surrounding foscarnet are resolved, and not before.

"We have discussed the situation with the FDA," contends Alf Larsson in Sweden. "We are in too early a stage to allow the use of foscarnet in an uncontrolled status," he says, echoing Karol and the FDA. "Everyone should blame us if we do not know the correct dosage," complained Larsson. "As soon as we have enough data we shall talk to the FDA." Larsson said Astra is trying to get the drug approved as soon as possible so that patients can have access to a treatment IND, adding in a plaintive tone, "We must have the data. Surely you must see that?"

After talking with Astra several times, Elliot is not altogether convinced that safety concerns and the FDA are all that hold Astra back from applying for compassionate use distribution. Sutton says that Jim Hedges, another Astra official in the U.S., said flat out to him: "Astra is not going to get caught in the same way Syntex is." Hedges told *Coming Up!* he doesn't remember making the comment.

Getting caught means three things to Astra. First, it means if foscarnet is given to one person it must go to everyone. Second, if they give it out on a compassionate use, Astra has to pay for it. Third, if the drug is available on compassionate use, Astra and other companies are worried the data they collect will not be good enough for the FDA. They also worry that patients will not be interested in joining the trials. After all, what is in it for a drug company if compassionate use will not help get the drug licensed with the FDA?

Elliot is beginning to suspect Astra "may be using the FDA as a scapegoat for financial reasons... The thing I cannot tolerate is the fact that for financial reasons, or confusion with the FDA, Astra is unwilling to go to the extra effort to make it available for me and other people going blind. It is unethical."

Until the salvage protocol begins there is only one place for ganciclovir failures to go. Astra is running a salvage trial in Houston that patients have to pay all the bills for apart from direct Astra lab work, making foscarnet, very simply, a remedy only for the wealthy.

The Ghostly Greenbacks

Drugs are expensive, clinical trials prohibitively so, and those for foscarnet and ganciclovir are no exception. At San Francisco General Hospital alone, Dr. Jacobson estimates ganciclovir trials alone have cost some $500,000. Jacobson says the only reason there are any beds for the foscarnet studies currently running is because the SFGH-based clinical research group has donated one of its six beds to the trials on a regular basis. Volunteer surgeons embed the internal catheter needed so drug infusion is possible. All this is over and above the cost of the drug but absolutely necessary for the treatment and protocol.

Dr. Jacobson singled out MediCal's refusal to pay for hospital costs associated with investigational drugs as the single most important reason not enough research is being done on foscarnet, ganciclovir and other drugs for AIDS. He argued that MediCal consistently decertifies hospital charges associated with individuals on drug trials, thus leaving the expense in the lap of an already overburdened San Francisco.

MediCal chief of policy Dr. George Wilson, flatly states experimental services are not covered. MediCal will cover the cost of drugs for treatment INDs, but not the associated care expenses. Wilson says many of the hospitalizations required by the protocols could be covered on an outpatient basis and should not be charged to the hospital because they are not direct medical necessities, but instead are part of an experimental treatment not covered by the MediCal charter. "We are not anti research," he says, "but there are many millions available for AIDS research. The funds going to health care for the poor are not geared to basic research."

Dr. Peter Sullivan who has taken up the gauntlet of challenging MediCal decertifications is fighting a running battle with the state agency. He ridicules Wilson's contention that a person on a ganciclovir infusion doesn't need hospitalization, saying anyone needing three infusions a day needs to be in hospital. He charges, "It makes incredible financial sense for the state to dump the responsibility for care on the city without giving the finances. The state has universally shirked it's responsibility."

Richard Chambers, director of intergovernmental affairs for the Health Care Financing Administration in Washington D.C., the federal wing of the Medical program, said Medicaid would reimburse state to pay for INDs, but he threw the responsibility for the decision about paying for hospital costs back to the state.

In the field of private insurance, both Blue Shield and Blue Cross said they cover drugs recognized as a treatment IND, but not experimental drugs, thus they could pay for ganciclovir but not foscarnet.

And the bouncing ball continues. No one is able or willing to to take financial responsibility for the costs of clinical protocols on foscarnet and ganciclovir. Everything is on hold until a treatment IND is granted for foscarnet.

Despite the grim financial picture, the issue of patient access to foscarnet is moving more quickly than any other drug for AIDS barring AZT. Foscarnet and CMV retinitis were barely on the agenda two years ago; now they are at the top of the list. For the first time, the debate in Washington is starting to include what people with AIDS have been demanding all along: the recognition that people with life threatening illnesses have a right to make choices about their treatment, and a re-examination of the policies determining patient access to promising drugs. But whatever action is taken must be taken quickly. As Steve Morin warned "The clock is ticking and these people are going blind."

The CHAIRMAN. Dr. Williams said, "You give them a drug, and their pain goes away, they eat again." He says, "It is very obviously cause and effect."

You bear a very heavy responsibility. But I would say that we had this information last July, and we are now several months down the road on it. You get increasing indications by medical professionals that it is effective, it is working. Clearly, for those who have been treated with it and had positive experiences, it has had enormous impact in relieving the pain and anguish and suffering.

You said here, that you are going to be visiting with Dr. Fauci, we would be very interested in finding out the results of that particular meeting, and if you would send a communication to the committee detailing the status and the next steps, we would all very much appreciate that.

Dr. YOUNG. I would be happy to do that. As it was quoted in the paper, I did have a meeting with the staff and FDA yesterday; I have been in contact with Dr. Fauci. We want to bring in some of these investigators who have this evidence and have that evidence put into the file with FDA and see whether we have enough information to make an evaluation. And I shall communicate that to you.

The CHAIRMAN. Fine.

I will yield to my colleagues. I do have some questions with regard to personnel and building and some of the other details which are enormously important, but I will be glad to yield to my colleagues.

Senator ADAMS. Mr. Chairman, I want to support your position, but I would like to defer to my colleagues who were here prior to my entering the room.

The CHAIRMAN. Senator Mikulski?

Senator MIKULSKI. Thank you, Mr. Chairman.

First, Dr. Young, congratulations on your reappointment by the administration—you have been reappointed, right?

Dr. YOUNG. Oh—I am not exactly sure I saw the same paper that you did, with the chief of staff making an appointment. I think once the Secretary is there, that will be completely clarified, but I thank you for your well wishes.

Senator MIKULSKI. Well, we govern by newspaper, anyway, so why not this, right—and TV.

Dr. Young, obviously, what we wanted to accomplish in S. 1220 was to provide more workers at FDA and to try to implement some of the things that came out of the Watkins report. Listening to you today, I can very clearly see that you and your team really had the will to try to come to grips with these issues.

Dr. YOUNG. Unquestionably.

Senator MIKULSKI. I am unquestioning about it as well.

My question to you is, first of all, Doctor, were adequate resources provided to you in terms of personnel, the need to upgrade laboratory equipment, not only in the AIDS process, but because of our new advances that are coming out of NIH; you are obviously overwhelmed with requests for these INDs.

So the question is as to adequate personnel, adequate resources in terms of your laboratories and your facilities.

The Watkins report talked about immediately authorizing and appropriating 50 FTEs to help you out. They talked about providing additional office and laboratory buildings for you and so on.

Do you feel that you have the resources, first, that have been authorized and appropriated; and then second, in the budget that is being proposed for fiscal year 1990, are they there—or are you, as I find in my visits with NIH, being hamstrung my OMB, meaning we authorize, we appropriate, and then they set FTE limits and defer. Now, that last point you might not wish to answer until you have been reappointed. [Laughter.]

Dr. YOUNG. I am not sure whether I want to answer the whole thing.

Senator MIKULSKI. Well, Doctor, what I am trying to get a picture of is, given now the will, the fact that you are attempting to set up communication mechanisms, you need the wherewithal to do it. According to the Watkins report, it takes at least 10 to 12 months to train an adequate examiner.

Dr. YOUNG. Yes, it does.

Senator MIKULSKI. You cannot just throw somebody in with a bachelor of arts degree in biology or something. So that is my question—we are giving you the mandate; are the resources coming from both the Congress and the Executive Branch?

Dr. YOUNG. Senator, because of the delicate position of the President making his budget presentation this week, I will refrain completely from the 1990 and will speak only during the Reagan administration years.

Senator MIKULSKI. Fine.

Dr. YOUNG. I will also try in general to give the intensity of the feeling that FDA has and then answer your question specifically.

The hardest thing for the agency is that the rate of increase in workload has been unexpectedly high, and we find it very difficult to know how to prepare a budget. In the last couple of years, 1988 and 1987, we have been very pleased that by and large the numbers that we have requested for FTEs have been forthcoming.

There are two difficulties, though. First of all, we cannot anticipate two years ahead. A couple of years ago, I never would have thought that we would have to increase blood supply inspections to every year instead of every other year and find the difficulties that we found and do inspection upon inspection upon inspection. That resulted in an immediate need, which I was asked to communicate to the Senate and to the administration, for 69 people. This need was never anticipated or planned for.

We never anticipated the intense problem with the condoms and rubber gloves.

With regard to the drugs, we never expected to see a doubling every year of the number of new applications coming in. And you are absolutely right, it takes about a year to bring these people on line.

Senator MIKULSKI. Well, first it takes time to find out who wants to come to work for the Federal Government with that kind of background. Scientists just are not out there in food stamp lines right now, looking for jobs.

Dr. YOUNG. That is right, and we are in the vortex of controversy.

Senator MIKULSKI. You have got a work force shortage; then you have got to recruit them at the pay—are these some of your problems—

Dr. YOUNG. Yes, they are.

Senator MIKULSKI. And then, when you get them, you have got to train them—and keep them.

Dr. YOUNG. And they can leave for salaries that are four to five times higher once they have been trained in FDA—an enormous problem.

Senator MIKULSKI. Four to five times?

Dr. YOUNG. Four to five times, yes.

Senator MIKULSKI. What do you pay? We are fascinated with this topic, you know; we are mesmerized by it; we are gripped by it. [Laughter.]

Dr. YOUNG. Well, I can tell you that if you look at the agency, you would bring a person in without the physician's comparability in the mid-sixties. After you go out, with 6 to 7 years of training in FDA, you can do quite well.

Senator MIKULSKI. Are you talking about $200,000 a year?

Dr. YOUNG. Yes, yes; not a problem.

Senator MIKULSKI. Mr. Chairman, we majored in the wrong thing.

Dr. YOUNG. A little bit higher than Senators are paid.

The CHAIRMAN. If the Senator would yield, Dr. Weingarden said that they had not been able to recruit a senior scientist at NIH in the last 10 years.

Dr. YOUNG. That would be true at FDA.

The CHAIRMAN. And the flow out in terms of top scientists/researchers is at an all-time high. And here we are, appropriating hundreds of millions of dollars for scientific research in areas of enormous need, and we are losing top-flight people.

Senator HATCH. Can I just add to that. I just learned that in our armed services, there is a bonus program that is rewarding plastic surgeons and general surgeons. However, board-certified gastroenterologists and others are only being paid $50,000 or $60,000 per year. It is likely that they are going to start leaving the services in droves. Retention will be a big problem.

Then take FDA—not only do you not pay adequate salaries, but you do not have the appropriate equipment. I was shocked to find you are not currently on a computerized system. I am not blaming you; I think it is our fault. Your filing systems are state-of-the-art as of about 1930, because they are not computerized. If a new drug application comes in, it may be 100,000 pages; but it still must be reviewed by rote rather than on the computer.

To make a long story short, it is very difficult to get the top scientists, top lawyers, top doctors, top engineers to work for the Government today, and especially in these technical areas.

The CHAIRMAN. I think it is.

Senator MIKULSKI. Reclaiming my time. Doctor, obviously, these are issues that are very much on the minds of the Senate, both the recruitment and retention of qualified personnel and the adequate facilities for you to do your job.

Dr. YOUNG. Absolutely.

Senator MIKULSKI. We know that President Bush will be coming before us on Thursday night for fiscal 1989. After he does that, I think, if I speak for this committee and for the Senate, we would really like to see what is a "must do" list for FDA to do this. And I would hope as you move around within the councils of our Government, we could really ask President Bush to give us a top science policy adviser, not only to pick and choose what we are going to fund—supercollider, space station, et cetera—but this issue of scientific personnel within our Government, whether it is space science, or NIH, or you, I think really jeopardizes our country.

So, please, I would really ask for the "must do" list and do whatever you can do in your own talking to help get us a good science policy adviser.

Dr. YOUNG. I will certainly respond positively to both of those and will provide that list.

The other thing that I must say is that the problem in FDA is different, in my opinion, than for any of the other agencies. We stand in the vortex of controversy. It is not a question of whether we are going to get hit on the head; it is on which side. And the degree of FDA-bashing is very difficult.

At the same time, whereas in other PHS agencies can take honoraria, as you can, we have no way——

Senator MIKULSKI. So far.

Dr. YOUNG. So far—we have no way to augment or enhance the salary.

Senator Hatch aptly said that there is a concern about military personnel and specialties. I want you to know there is no compensation listed there for drug reviewers. We are out of that. When the alarm goes off, we are not going to go and practice internal medicine. We are not maintaining those skills. So we are completely left out of that type of compensation at a time when the Nation is looking to FDA to be as vigorous and responsible—and trying to recruit, manage and deal with one hand and one leg hobbled. And it is very difficult at this point.

Senator MIKULSKI. Well, thank you.

Mr. Chairman, I am not going to ask any more questions. I think this goes to the heart of what we need to do for some of our agencies. I would hope that as we move along this year, we address the issue of highly skilled personnel as well as seeing that FDA and NIH and CDC get the resources they need, not only for AIDS but on high blood pressure and cancer and all the other challenges that these agencies are charged with.

Thank you very much, Dr. Young.

Dr. YOUNG. Thank you.

The CHAIRMAN. Senator Hatch.

Senator HATCH. Thank you, Mr. Chairman, and I appreciated the questions of our distinguished Senator from Maryland. As usual, they are cogent and right on the point.

But let me tell you something. When I went out to FDA—I happen to think FDA is the best agency in Government today—but I cannot begin to tell you how shocked I was to see how hampered you are. You are besought by everybody, because it takes up to 10 years to go through the safety and efficacy process alone, at costs of up to $80 million per new drug—maybe more. I was absolutely

shocked to find that you are located in 23 buildings around this town. How in the world can you coordinate an agency doing that? And you are not computerized—although you are starting some computer programs. I understand there are some companies who are willing to put up the money themselves to be able to tie into a computer at the FDA. Your filing system, although the best you can do under your budgetary constraints, is still woefully inadequate. You cannot find people who are willing to work for those salaries anymore, especially the qualified people you need to do this work. Yet FDA has overview of 25 percent of all the consumer products in America today if you include the food side with your responsibilities.

Dr. YOUNG. That is correct.

Senator MIKULSKI. What percentage?

Senator HATCH. Twenty-five percent.

Dr. YOUNG. It is $570 billion worth of industry per year.

Senator HATCH. It is the most incredible thing—and we treat you like you are some sort of a ragged, lost stepchild. It is unbelievable.

So that is why I want to compliment Senator Kennedy. He and I have been working on this FDA Revitalization Act which would, hopefully, bring you into one building which has state-of-the-art equipment. That alone would attract more qualified scientists.

Dr. YOUNG. Yes, it would.

Senator HATCH. The ones who are there, I give credit to. They have stayed there and sacrificed for our country all of these years. But these changes would attract new graduates. Then, if we could find some way of augmenting the salaries, this agency will continue as the greatest food and drug agency in the world—and frankly, the hallmark for the rest of the world.

But I am real concerned about it, and I know Senator Kennedy is, also, and we are going to do what we can.

With regard to computers, I know that you have some private sector approaches underway. Could you describe those and tell us what you would like to do?

Dr. YOUNG. Surely. This is what we are doing. First, the paper intensity when I came to the agency is just as you described, because fundamentally, the NDAs were being submitted as paper, and a 100,000-page application is—well, I can tell you, the AZT was 20 linear feet, and that was a short application.

Senator HATCH. Yes; that is not all that abnormal.

Dr. YOUNG. So that we are trying to bring these into computer systems. This is what we have computerized. We have the biopharmaceutical package computerized so that during pharmacokinetic reviews, we can run information back and forth with a company; that saves a lot of time. We send out the floppy disk, they put the data in, and then our scientists and their scientists can look at those. We are now working on a statistical problem.

Senator HATCH. So you can question back and forth on the computer.

Dr. YOUNG. Right. Instead of mailing things back and forth, you can question back and forth. It saves an enormous amount of time.

We have recently developed a tracking system for drugs and drug INDs. As I said, Dr. Parkman was going to do that in biologics, and we funded your clinical protocol program out of his con-

tract, so we will not be doing his tracking of biologic licenses and INDs. Fortunately, that was underway, but his $500,000 for that has gone into the AIDS bill to meet those needs.

I must say, anecdotally, Dr. Parkman is one of our best recruiters, because he has been able to get people to come in to remodel bathrooms. In his building, which is 100 people over the personnel ceiling, he has remodelled bathrooms, and has two people working in bathrooms and remodelled——

Dr. PARKMAN. Former cold rooms, also.

Dr. YOUNG. Former cold rooms, and things like that—he has done that.

Senator HATCH. Senator Kennedy, how can you, as chairman of this committee, allow this to continue, is all I can say. [Laughter.]

The CHAIRMAN. We will let you vote for that increased spending that we are so famous for.

Senator HATCH. Don't worry, I intend to. I intend to help our chairman. He is restraining me in this area.

Dr. YOUNG. As for other computerizations, about 31 new drug applications have come in, in part, on disk, and we found that that works much more rapidly.

Senator HATCH. If you had a completely computerized system, you would be a much more efficient agency.

Dr. YOUNG. It would be much better, because we have got rooms and rooms——

Senator HATCH. Is it true that in most of these cases, the companies themselves are putting up the computer systems so that they can have this kind of access?

Dr. YOUNG. They are helping us in providing the computers to the best of their ability. We cannot take too much because that would be conflict of interest, so we are really very, very careful.

Senator HATCH. I understand. Let me just ask one or two other questions, and I will be very short.

You have made great strides in releasing new drugs as they have become efficacious with regard to AIDS. Now, does that stand the same for other terminal illnesses as well?

Dr. YOUNG. We are trying to. We feel that the drugs for the desperately ill have the highest priority. We are moving now into working very closely with ADAMHA. We work exceptionally closely with NIAID. We are having trouble in trying to work as closely as we want with NCI, but Sam Broder and I are working more intensively there.

Fortunately, in the cancer realm, on my watch, drugs for cancer have been approved on the average in 7½ months from the time they reach the agency. So we are making good progress there. And last year, four of the 20 drugs were approved in under a year. The year before, two under a year; before that, we had no applications approved under a year. So we are making ground. And our complete focus is on drugs for the desperately ill. The "me-too" drugs are taking a backseat.

Senator HATCH Well, let me just say this. President Reagan's budget request includes a $100 million user fee plan. Do you have any other ways or suggestions for getting greater funding for FDA activities?

Dr. YOUNG. I don't know. I have tried very vigorously to look at some sort of a user fee, because it was the only way that I could see at this moment of bringing greater funding in. I think there is some good argument for that, because other countries use FDA as a gold stamp of approval. Getting an FDA approval in some developing countries is tantamount to being included in the Pharmacopeia. That is true in Pakistan, for example, and other countries. So many countries use FDA as their gold standard, and they do not pay, but the American taxpayer pays.

I think there has to be some way to increase the resources. The pharmaceutical industry pays for $25 million in research. In the *Post* either yesterday or today, there was an outline of their expenses, and they are spending more for research than NIH.

Senator HATCH. $25 billion, you mean.

Dr. YOUNG. No. Per day, I believe, it is $25 million.

Senator HATCH. Oh, per day, yes.

Dr. YOUNG. A single day's less research per year would provide roughly the amount of resources to cut the approval time within FDA in half three years after that was granted. And we are not talking about big bucks.

Senator HATCH. Well, let me just say this. At a recent meeting of the PMA, I challenged them to come up with some way that we might have a public/private partnership, without conflict of interest, that might help raise the funds to help FDA to have what it needs to do this job. I cannot speak for Senator Kennedy, but he and I have both chatted together. We would like to come up with some reasonable way of doing what needs to be done at this important agency.

I think the AIDS controversy and the AIDS tragedy really give us the spurring point to start doing some of the things that we are woefully inadequate at doing today.

We are going to follow up. We would like to hear from you regarding anything that your agency can do to help or suggest. We will go from there.

Mr. Chairman, I commented about everybody who is testifying today except my friend, Sam Thier, and I just want to welcome him as well and tell him how much we appreciate having him at these hearings.

Thank you.

Dr. YOUNG. I thank you, Senator. I should add that when Vice President Bush was chairing the Regulatory Reform Committee, he was very helpful in aiding FDA in its programs as well.

I look forward to your support, and I thank you for your encouragement, and I think your idea of a private/public resource, some sort of a trust or something might be of great value, because it would help keep our taxes down and may bring the right resources in.

Senator HATCH. It is to the advantage of all segments of this industry, because inefficiencies that naturally occur because of failure to bring FDA into these modern times, cost inordinate amounts of money. I do not blame anybody at FDA. I do not think it is your fault. It is our fault, up here, for not recognizing that and grabbing the bull by the horns and doing what has to be done.

I just hope that this AIDS set of tragedies will bring it home once and for all, to all Americans, that this agency is one little jewel in this overall Federal Government that we have got to continue to polish and keep right.

Dr. YOUNG. Thank you for your support.

The CHAIRMAN. Senator Simon

Senator SIMON. Thank you, Mr. Chairman.

First, I concur in what my colleagues have been saying on the need for moving as rapidly as we can.

As you look at this chart here, you go up to 250, and then you are up to 278 here. What should that number be in order to deal with that 250 number in INDs?

Dr. YOUNG. We already are spending approximately 80 beyond that right now. We anticipate—and I can submit that for the record—but I believe we are substantially overbearing on it.

Our problem, Senator, is that it is hard to know from year to year. We cannot predict what is going to come up. And there has to be, I believe, and as Admiral Watkins pointed out, some way to link the number of INDs with the number of people coming in, with some lead time.

One of the imaginative ways that I have suggested is that we need to have training grants and in regulatory medicine, so that we can have centers within the great universities where we can train people in this field and have faculty that we can bring in and out to aid us in some of the areas.

We need a mobile force, much more than we have, because we are playing catch-up, and we do not know what is going to be the right number until it hits.

The NIH appropriations do not even match, because NIH is only doing about 35 to 40 percent of the research on drugs, and the pharmaceutical industry is putting in much more.

So I think there has to be some linkage between the INDs and the number of individuals; that linkage has to extend to recruiting about a year in advance, because it takes a year to train them; and it has to be linked to a space projection so that we do not have to wait until the person is there an additional year before we can get the space. We have now doubled up in Ellen Cooper's Virology Unit, where you have people sitting across from each other in about 125 to 130 square feet of space. We have two per office, and her division is separated, with one portion in Parklawn and the other in another building.

These kinds of things make it very, very difficult for the agency. So that is the way I would think it could be done.

Senator SIMON. Do you get any kind of advance warning in an application at all? In other words, do they say to you, "Six months from now, we are going to be submitting an application," so that you can prepare at all?

Dr. YOUNG. Not very frequently. What I have been doing now is I meet with and will be meeting with probably 30 or 40 company CEOs per year, as I am projecting it, on drugs for the desperately ill. There, I will have some indication of the workload.

But a number of these just come in either as a completed application, that we may know it is out there, or as IND's filed by researchers because they have just discovered something new. And

now, with combination therapy, which is happening—it is not just interferon alone, but interferon plus AZT, as the chairman said—dealing with aerosolized pentamidine plus AZT plus interferon—these combination therapies are coming in now. So we do not get adequate warning. And therefore, I think we need some sort of a mathematical model to project our personnel and space needs, so that we can stay ahead.

Up to this time, I feel that we have been running behind, not through anyone's fault, but because workload is just outstripping our capabilities.

Senator SIMON. Assuming that 250 were just to stay flat, which seems unlikely——

Dr. YOUNG. It is doubling every year.

Senator SIMON. Yes, but even if it were just to stay flat, is the 358 number that you now have adequate for the 250?

Dr. YOUNG. I would have to make some more calculations. That is difficult to answer off the top of my head, because I have to adjust, as you can see, for devices and the work on blood banks in the field. You see, that is not just the reviewers alone. That 278 number that you see there takes in over 100 people working outside of drugs and outside of biologics. It is very complicated.

Senator SIMON. I notice in your testimony you have four applications for vaccines.

Dr. YOUNG. Yes.

Senator SIMON. Now, as a layman, a smallpox vaccine means to me you prevent that from occurring. Do you have four applications for vaccines that they believe they can prevent AIDS from occurring?

Dr. YOUNG. There are four applications from two major companies, and I will ask Dr. Parkman, who has spent his life working on measles vaccine, to provide further information on it. These applications are designed primarily at this time to look at safety. There is no good animal model that we have. So to go into an effectiveness test will be very hard.

It is likely that effectiveness will be studied in large populations, some of whom are vaccinated and some of whom are not. So the safety studies are underway.

I must say that I have received considerable criticism for allowing FDA to approve these in the absence of an animal model. But we felt the safety trials should go on.

It is thought, I think, by scientific consensus—and you would want to ask Dr. Thier this—that it is going to be very difficult to develop a vaccine. At this moment, there is not a high degree of promise. But Paul, this is your field. Could you comment on that, please?

Dr. PARKMAN. Well, the four INDs that were mentioned in the pie chart that you saw are two each for two products. They are both produced by recombinant DNA techniques. In one of them, the AIDS material is incorporated into the smallpox vaccine we all used to receive; those are in early clinical studies right at the moment.

As Dr. Young says, these studies are important, and the preliminary data show that the materials will produce biological effects. But we do not know whether these effects would be protective or

not. So, as Dr. Young said, the animal models are very critical to helping us know which way to go with these. People are working very, very assiduously trying to develop models for these AIDS proteins that will give us some kind of guidance as to where to go.

Senator SIMON. Have the pharmaceutical companies tried these on animals before, before they make application to you?

Dr. PARKMAN. Yes.

Dr. YOUNG. Yes, they have. But they are looking at whether or not there is an antibody response. They are not looking in any way at whether effective protection has occurred. It is very good to get a good animal model that will show protection at this point.

Senator SIMON. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. On the chart there, in the blue, you have got 135 FTEs; "FOI" usually means Freedom of Information. Is that what they are doing there?

Dr. YOUNG. Yes.

The CHAIRMAN. So you have got more working on Freedom of Information than you have AIDS; you have 123.

Dr. YOUNG. Yes. It is fascinating, Senator.

The CHAIRMAN. It certainly is.

Dr. YOUNG. We stand second only to the entire Department of Defense on Freedom of Information requests, and 87 percent of that is for industrial espionage. I think this is one of the poorest uses of taxpayers' dollars that I have seen.

In fact, if you read the pink sheets, grey sheets, brown sheets, you will see where to send for Freedom of Information materials from the Food and Drug Administration, commercially.

The CHAIRMAN. Well, we have members of the Judiciary Committee here; why don't you have your legal counsel give us a note on that—would you?

Dr. YOUNG. I would be delighted. This has been a concern, not because we don't want to bring good information to consumers. But when 87 percent of it is for industrial espionage, one company trying to find out what the other company is doing, and then other companies selling this for profit, on the backs of FDA FTE's, it seems unusual.

The CHAIRMAN. We will submit other questions, but you have taken a good deal of time, and we have other witnesses. So I do want to thank you—and you will follow up with those other requests?

Dr. YOUNG. Yes. And just for the record, I did not put the "FTE Adjusted Workload" slide up there. I am not sure exactly where that came from, but mine were over there.

The CHAIRMAN. Okay. Thank you very much.

Dr. YOUNG. Thank you very much, Senator.

The CHAIRMAN. I know Dr. Thier has very little time before he has to leave. We will take his testimony now.

Dr. Thier, if you would like to take just a few moments to summarize it, we would welcome that. We are mindful that you have a very, very pressing and important engagement, so I apologize to you, Doctor. We got a later start today, and I know you have to go.

We will put the whole statement in the record, and if you want to give a brief summary, and then we will submit all of our questions to you at a later time.

STATEMENT OF DR. SAMUEL THIER, PRESIDENT, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, WASHINGTON, DC

Dr. THIER. Thank you very much, Mr. Chairman.

As you know, the issue is one of some urgency, that is, the resources for combating the epidemic of HIV infection.

I think it is necessary to point out that if we monitored the attention paid to AIDS in the media, we might think the epidemic was waxing and waning. The interest in coverage seems to rise and fall, but the sad facts are that, regardless of the amount of public attention, the number of AIDS cases has tracked remarkably closely to CDC's projections over the past 3 years. They rise inexorably, and promise to result in 200,000 deaths in the next for years alone.

The Institute has been interested since 1985 in tracking the epidemic and in assessing the Nation's response. We have utilized our usual system of panels of experts from fields such as biomedical and social sciences, public health, health economics and such, and my general remarks reflect the best judgments of those groups.

I would like to focus on three areas—the educational efforts to foster and sustain behavioral change, which are the only practical means now available to stem the spread of HIV infection. I think it is critical that we remember from the history of other sexually-transmitted diseases that even effective drug therapy is unlikely to eradicate HIV-related diseases, and therefore, understanding and preventing behaviors that transmit HIV will continue to be crucial even after successful development of drugs and vaccines.

Information about the modes of transmission must be conveyed in an understandable, scientifically accurate form. The message of AIDS education programs must address sexual behavior and drug matters that are regarded by some as morally unsuitable for description in public health campaigns.

Unsubstantiated concern that frank, straightforward educational programs can enforce drug abuse or sexual relations has stymied educational efforts. However, explicit information on the risks associated with unsafe sex and drug abuse and the way those risks can be minimized has not been shown to promote or encourage such activities. Its sole function is to avoid an illness that endangers lives and costs billions of dollars.

Government at all levels will have to continue to fund factual educational programs designed to foster behavioral change. This may mean supporting AIDS education efforts that stress not only abstinence, but also that contain explicit practical and perhaps graphic advice targeted at specific audiences about safer sexual practices and how to avoid the dangers of drugs and of shared needles and syringes.

This is the approach followed in the United Kingdom and most of Western Europe.

The urgency of the epidemic warrants a multiplicity of educational efforts. A number of Federal Government entities currently spend more than $300 million yearly for advertising. However, ad-

ministrative restrictions at HHS have prevented CDC from paying for advertising in the past. The recently enacted amendments of 1988 allow the CDC to purchase advertising time. We urge them to do so and strongly encourage the administration to make certain that funds are supplied to that purpose.

In 1986, we recommended that approximately $1 billion be spent annually for education and other public health measures by 1990. Although this figure represented a goal for total national expenditures including funds from private sources, we felt that a major portion should come from Federal sources, because only national agencies are in a position to launch coordinated efforts commensurate with the size of the problem.

In our updated 1988 recommendations, we recognized that these estimates were in fact low, and despite the fact that there were major improvements, significantly more than $1 billion was going to be required. The reason that this was true is that we had underestimated the impact and the importance and the costs of attacking the problems of IV drug abuse and the fact that it had now become the major route of spread into the heterosexual community and the major spread to newborns.

What is needed in education is a massive effort, fully exploiting the best scientific understanding of effective methods to change behavior, and it must include evaluation components so we can focus the resources on what works best for what populations.

The care of persons infected with HIV poses a great challenge to our health care system. The relatively sudden appearance of large numbers of young, extremely ill individuals has highlighted the inadequacies of our total health care organization and financing.

We outlined a model of patient care comprising appropriate inpatient care for those acutely ill and comprehensive community and home-based outpatient care as early as 1986. We believe that the evidence from that time has indicated that that approach is in fact even more useful today.

The average lifetime medical costs of AIDS cases now range from $65,000 to $80,000 total in 1987 dollars, but in areas of the country where hospitalizations are minimized because of greater reliance on community support services, medical care costs are substantially reduced.

Unfortunately, reimbursement for medical care under our present system is based to a large extent on episodes of hospitalization, thus driving the kind of care toward this expensive and sometimes unnecessary but reimburseable form of care.

In our updated 1988 report, we recommended the Federal Government undertake a grant program to States to ensure that AIDS patients and those with HIV-related conditions have access to appropriate and cost-effective care. This approach is clearly stopgap, it is clearly interim. It will not substitute for developing comprehensive financing programs for patients with AIDS and other calamitous illnesses.

In the AIDS amendments of 1988, Congress took an important step in this direction by authorizing the appropriation of $100 million annually for formula grants to States for home, community-based health services. However, we are disappointed to learn that the funds for this much-needed program did not appear in the ad-

ministration's budget for 1990. We hope that President Bush in his forthcoming amendments will support this program and that the direction Congress has already taken in their approach to AIDS and patient care will be endorsed.

Even in the best of times, the role of the FDA is a difficult one. The FDA must at once protect the American public from ineffective or potentially toxic new drugs, by strictly regulating their release into the marketplace, while speeding safe and effective new drugs through the system so that they can quickly benefit the patients who need them.

With AIDS, the tensions inherent in this mandate have increased tremendously. Our review in the early years did not indicate that FDA was the bottleneck in availability of new drugs to treat HIV infections and AIDS. The paucity of new drugs to that date unfortunately was related to shortcomings in the science of antiviral agents and anti-HIV vaccines more than to drug approval processes.

However, as you have seen, many promising new drugs are now in early stages of development, and the FDA without additional resources could become an impediment to speedy availability.

New regulations for investigational new drugs may in fact speed availability, but they also stress the resources of the FDA, including space and personnel. FDA resources must be kept commensurate to the task of timely and thorough evaluation of new drugs for HIV infections and AIDS.

Investment in research directed at drug and vaccine development for HIV must be coordinated with investments of the FDA's capacity to evaluate products of that research. To invest $1 billion in developing new antiviral agents and vaccines and then not allowing for the resources to FDA to evaluate those products use not a coordinated, wise approach. We hope there will be an exciting spirit of cooperation between the administration and Congress. I hope you can grasp the opportunities this cooperation offers. It is time for us to harness our knowledge and resources and to finally stem the tide of this terrible epidemic.

Thank you.

[The prepared statement of Dr. Thier (with attachments) follow:]

Testimony of

Samuel O. Thier, M.D.
President, Institute of Medicine
National Academy of Sciences

Senate Committee on Labor and Human Resources
February 7, 1989

Resources for AIDS Education, for Care of Patients with AIDS and HIV Infection, and for the Food and Drug Administration

Mr. Chairman and distinguished committee members, I am pleased to address you this morning on a topic that I view with great urgency -- resources for combatting the epidemic of HIV infection and AIDS. As you know, the Institute of Medicine and the National Academy of Sciences have been studying the epidemic, assessing the nation's response to it, and recommending needed action since 1985. In undertaking these responsibilities, we have convened panels of scientists who represent all the disciplines crucial to understanding and meeting the challenges posed by the epidemic -- biomedical and social scientists, public health experts, health economists, experts in education, and professionals from many other fields. I emphasize the composition of our panels because it is important to understand that the resulting recommendations represent broad consensus among the most accomplished individuals in a great variety of fields relevant to the AIDS epidemic. My remarks today on resources for education, medical care, and the Food and Drug Administration, reflect the accumulated wisdom of these groups, who have been meeting and working intensively for the past three years.

Educational efforts to foster and sustain behavioral change are the only practical means now available to stem the spread of HIV infection. The history of other sexually transmitted diseases teaches us that even effective drug therapy is unlikely to eradicate HIV-related diseases, and therefore understanding and preventing behaviors that transmit HIV will continue to be crucial even after the successful development of drugs and vaccines. Information about the modes of HIV transmission must be conveyed in an understandable, yet scientifically accurate form. The message of AIDS education programs must address sexual behavior and drug

abuse, matters that are regarded by some as morally unsuitable for description in public health campaigns. Unsubstantiated concern that frank, straightforward educational programs can encourage drug abuse or sexual relations has stymied educational efforts. Explicit information on the risks associated with unsafe sex and drug abuse and the way those risks can be minimized does not promote or encourage such activities. Its sole function is to help people avoid an illness that endangers their lives and those of their sexual partners and children, and costs the nation billions of dollars.

Government at all levels should continue to fund factual educational programs designed to foster behavioral change. This may mean supporting AIDS education efforts that contain explicit, practical, and perhaps graphic advice targeted at specific audiences about safer sexual practices and how to avoid the dangers of drugs and shared needles and syringes. This is the approach followed in the United Kingdom and in other Western European countries.

In addition, more studies are needed to determine the effects of various types of educational campaigns on specific populations. The rigorous evaluation of intervention programs is an essential component of AIDS education. Without scientifically designed and well-funded evaluations of various educational strategies, we will be no further along in understanding which methods work to change risk behavior.

The urgency of the HIV epidemic warrants a multiplicity of educational efforts, including the use of paid advertising to convey all types of

AIDS-prevention messages on television and in other media. A number of federal government entities, including the military, the postal service, Amtrak, and the U.S. Mint, currently spend more than $300 million yearly for advertising. Administrative restrictions from the Department of Health and Human Services have precluded the Centers for Disease Control (CDC) from paying for advertising in the past; the recently enacted AIDS Amendments of 1988 now allow the CDC to purchase advertising time. We urge the CDC to purchase advertising for educational messages, and strongly encourage the Administration to make certain that funds are supplied to do so.

In 1986 the IOM/NAS recommended that approximately $1 billion should be spent annually for education and other public health measures by 1990. Although this figure represented a goal for total national expenditures (including funds from private sources), the committee felt that a major portion of this total should come from federal sources, because only national agencies are in a position to launch coordinated efforts commensurate with the size of the problem. In the updated 1988 recommendations we recognized that the $1 billion dollar a year figure was too low. A substantial sum of money will have to be spent, over and above $1 billion a year, to provide treatment facilities for IV drug abusers and to support programs to prevent drug abuse and to mitigate the dangers of shared injection equipment. In 1986, we called the magnitude of funds and effort being expended "woefully inadequate" to the task at hand. By 1988, there were major improvements in the federally-supported educational efforts, but the shortfall is still considerable. What is needed is a massive educational effort that fully exploits the best scientific

understanding of effective methods to change behavior. Educational programs must include an evaluation component so that we will know more about effective methods as the programs evolve.

Caring for persons infected with HIV poses a great challenge to the American health care system. The relatively sudden appearance of large numbers of patients with a disease notable for its medical complexities and thorny social and ethical issues has highlighted inadequacies in current medical practice and in the way health care is financed. In the Institute of Medicine and National Academy of Sciences 1986 report, Confronting AIDS, our committee outlined a model of patient care comprising appropriate inpatient care for those most acutely ill and comprehensive community and home-based outpatient care. Guiding the construction of that model was the principle that, to the greatest extent possible, care should be delivered in the community, rather than in hospitals or clinics, to make it both more humane and more cost-effective. The more we learn about HIV infection and its sequelae, the more we are convinced that this approach is sound.

The average lifetime medical costs per AIDS case, from diagnosis to death, are estimated to be between $65,000 and $80,000 in 1987 dollars. In areas of the country where hospitalizations are minimized because of greater reliance on community support services, medical care costs can be substantially reduced. Unfortunately, reimbursement for medical care under our present system is based to a large extent on episodes of

hospitalization, thus driving the kind of care provided toward this expensive and sometimes unnecessary, but reimbursable form of care.

In the IOM/NAS report Confronting AIDS: Update 1988, we recommended that the federal government undertake a grant program to states to ensure that AIDS patients and those with HIV-related conditions have access to appropriate and cost-effective care. This approach was viewed by our committee as an interim solution to the problem of financing AIDS care, yet one that would offer some financial relief to those states and medical institutions that currently bear a disproportionate burden of AIDS care. In the AIDS Amendments of 1988, Congress took an important step in this direction by authorizing the appropriation of $100 million annually for formula grants to states for home and community-based health services. The design of this program displays a recognition that such services as homemakers and health aides, day treatment, home intravenous drug therapy, and the administration of routine diagnostic tests in the patient's home contribute to cost-effective and higher quality medical care. However, we were disappointed to learn that the funds for this much needed program did not appear in the Administration's budget for 1990. We urge President Bush, when considering his forthcoming amendments, to support this program and the wise direction Congress has taken in their approach to AIDS patient care.

Even in the best of times the role of the Food and Drug Administration is a difficult one. The FDA must at once protect the American public from the potentially toxic side effects of new drugs by strictly regulating

their release into the marketplace, while speeding safe and effective new drugs through the system so that they can quickly benefit the patients who need them. With AIDS, the tensions inherent in this mandate have increased tremendously. We believe that the FDA has not been a "bottleneck" in the availability of new drugs to treat HIV infection and AIDS. The paucity of new drugs is related more to shortcomings in the science of antiviral agents than to the drug approval process. However, many promising new drugs are in early stages of development, and FDA, without additional resources, could become an impediment to speedy availability. New regulations for investigational new drugs will stress the resources of FDA, including space and personnel. FDA resources must be commensurate to the task of timely and thorough evaluation of new drugs for HIV infection and AIDS.

There is an exciting spirit of cooperation evident between the new Administration and Congress. I urge you to grab the opportunities this energy and cooperation offer, to harness our knowledge and resources, and to finally stem the tide of this terrible epidemic.

(I would like to give you a copy of the white paper on HIV Infection and AIDS, prepared for President Bush by the Institute of Medicine and National Academy of Sciences, so that it will appear in the proceedings of these hearings.)

Thank you.

HIV Infection and AIDS

Recommendations for President-Elect George Bush

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

The Honorable George Bush
The President-Elect of the United States
Old Executive Office Building
Washington, D.C. 20501

Dear Mr. President-Elect:

During your term in office, AIDS will claim over 200,000 American lives. It is estimated that 1 million to 1.5 million Americans, mostly young adults, are infected; in the absence of effective therapy, most will die. Your Administration can take several actions to slow the spread of this unprecedented epidemic and limit its damaging effects on this and other countries. The Institute of Medicine and National Academy of Sciences have prepared the enclosed white paper to help you meet this challenge.

The white paper draws from the Institute of Medicine and National Academy of Sciences study, *Confronting AIDS: Update 1988*, issued last June. The AIDS Oversight Committee, a panel of nationally recognized professionals, conducted that study and would be glad to serve you in any further advisory capacity. The Presidential Commission on the Human Immunodeficiency Virus Epidemic, as you know, also issued its report last June, and the broad concurrence of the two reports gives added weight to their findings. Until the newly legislated national commission on AIDS is established, the IOM/NAS committee is the only standing committee of national stature charged with assessing the nation's progress against the AIDS epidemic.

The program detailed in the white paper entails actions by various individuals. However, you and your Secretary of Health and Human Services can take the lead early in your terms of office by providing overarching direction for all segments of the government and the private sector.

Presidential actions should include the following:

- Use the newly legislated national commission on AIDS to develop a forceful and coherent national policy.
- Encourage the enactment of legislation to protect HIV-infected persons from discrimination in the private and public sectors.
- Express your strong support for an aggressive, unambiguous education program (as is occurring in Western Europe) about behavior changes necessary to avoid HIV infection. Use your influence to ensure that government at all levels provides funds for appropriate education in the schools and messages in the media.
- Express your belief that testing for HIV infection should only be conducted when the purpose of the testing is clear, and when the test results allow effective and humane interventions that would not have been possible in their absence.
- Recognize this country's special responsibility in international efforts to control the spread of HIV infection.

Your Secretary of Health and Human Services should be directed to:

- Develop a comprehensive, private-public (federal, state, and local) national plan for delivering and financing care for HIV-infected and AIDS patients.
- Initiate a forceful program for the prevention and treatment of drug abuse and prevention of the related spread of HIV infection.
- Bolster efforts in surveillance, case reporting, and the gathering of information about risk behavior.
- Ensure that biomedical research (including drug and vaccine development and regulation) continues to follow productive paths.

A crucial element in the task ahead is the tone set by the President. Vigorous measures are required to control the disease and to improve the social conditions (poverty, drug abuse, lack of education, etc.) that sustain it. The nation's leader, speaking from his unique position to inspire action against the disease among all the people, must balance this call to action with a concern for the civil rights of all.

Americans have generated an enormous fund of knowledge about AIDS. We know its cause, we can test for the presence of HIV in the body, and we know what measures would, if successfully applied, slow its spread. Furthermore, the scientific understanding that lays the groundwork for the development of effective vaccine and drug treatment grows daily. Yet despite these triumphs, we have not successfully confronted the epidemic. Your Administration inherits the opportunity to harness our knowledge and turn the tide against AIDS.

Yours sincerely,

Frank Press
President
National Academy of Sciences

Samuel O. Thier
President
Institute of Medicine

Attachment

HIV Infection and AIDS

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES

National Academy Press
Washington, D.C. 1988

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The National Academy of Sciences (NAS) is a private, self-perpetuating society of distinguished scholars in scientific and engineering research, dedicated to the furtherance of science and technology and their use for the general welfare. Under the authority of its congressional charter of 1863, the Academy has a working mandate that calls upon it to advise the federal government on scientific and technical matters. The Academy carries out this mandate primarily through the National Research Council, which it jointly administers with the National Academy of Engineering and the Institute of Medicine. Dr. Frank Press is President of the NAS.

The Institute of Medicine (IOM) was chartered in 1970 by the NAS to enlist distinguished members of appropriate professions in the examination of policy matters pertaining to the health sciences and to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education. Dr. Samuel O. Thier is President of the IOM.

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PREFACE

Early in 1988, the Presidents of the National Academies of Sciences (NAS) and Engineering (NAE), and the Institute of Medicine (IOM), with the concurrence of their Councils, decided on the preparation of a small number of "White Papers" for the incoming Administration. The intent was to summarize concisely a few critical national and global issues to which science and technology were central, and to suggest presidential options on these issues.

AIDS emerged at once as a leading candidate for such a paper. The IOM and NAS have been involved with assessing the nation's response to the AIDS epidemic since 1985, and have published two reports (*Confronting AIDS: Directions for Public Health, Health Care, and Research* and *Confronting AIDS: Update 1988*) recommending needed action. The second of these two reports, published in June 1988, served as the basis for the AIDS white paper.

Drafts of the paper were reviewed and discussed by the IOM AIDS Activities Oversight Committee,* the group that conducted the second IOM/NAS AIDS study and that oversees AIDS activities at the IOM, and by the Councils of the IOM and NAS. The views elicited in those discussions greatly influenced the subsequent evolution of the white paper and its final formulation.

The paper was written by Robin Weiss, Director for AIDS Activities at the IOM.

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During the next 4 years in this nation, the epidemic of human immunodeficiency virus (HIV) infection and its most severe manifestation, acquired immune deficiency syndrome (AIDS), will claim over 200,000 lives. The U.S. Public Health Service estimates that 1 million to 1.5 million people are currently infected with the virus. In the absence of effective therapy, the vast majority of those infected will develop AIDS and die. Although AIDS now kills fewer people than heart disease or cancer, its rank as a cause of mortality is quickly rising, and the primary sufferers of AIDS come from what is ordinarily a healthy and productive population group: young adults.

Stemming this agonizing epidemic requires presidential leadership. The epidemic poses dilemmas both for the public and private sectors that will best be solved by forceful, coherent national policy. The obligation to formulate AIDS policy spans a variety of federal government departments, and reaches beyond the Department of Health and Human Services to the departments of Justice, Education, State, Defense, Energy, the Veterans Administration, and other components of the Executive Branch. In addition, private organizations, foundations, volunteer groups, professional organizations, and state and local governments already have taken the initiative to create educational programs, formulate laws and regulations, and address other aspects of the epidemic. These efforts are an enormous contribution to the progress that has been made thus far against HIV infection and AIDS. Nevertheless, the absence of coherent national direction condemns many localities to begin anew when it comes to setting local policy, and increases the likelihood that failed experiments will be repeated from place to place. Your Administration can furnish overarching direction for all segments of the government and the private sector. Equally important, the President can set a tone that encourages aggressive action yet resists hysteria and insensitivity to the civil rights of infected persons.

Furthermore, foreign leaders will turn to the President of the United States for assistance and wisdom in addressing their own countries' HIV problems. The World Health Organization estimates that between 5 million and 10 million persons are infected with HIV worldwide. By 1991 AIDS may double the mortality rate for young and middle-age adults in some developing countries, and perinatal transmission in these countries may reverse hard-won advances in child and infant survival.

This paper proposes that your Administration take several actions, which we believe will help slow the spread of HIV and limit its damaging effects on this nation and on other countries: (1) use the National Commission on AIDS effectively; (2) protect HIV-infected persons from discrimination; (3) develop a comprehensive plan for financing the care of those with HIV infection and AIDS; (4) initiate a forceful program for the treatment of substance abuse and the prevention of the associated spread of HIV; (5) institute aggressive and unambiguous educational programs and evaluate their effects; (6) ensure that HIV

testing and other public health measures are employed only when their purposes are clear and their results productive; (7) bolster efforts in surveillance, case reporting, and the gathering of information about risk behavior; (8) ensure that biomedical research (including drug and vaccine development and regulation) continues to follow fruitful paths; and (9) recognize our special responsibility in international health efforts to control AIDS.

1. Use the National Commission on AIDS Effectively

The President has recently signed into law the AIDS Amendments of 1988, which establish a National Commission on Acquired Immune Deficiency Syndrome. Although the creation of a national commission is an important step, the commission's existence alone does not guarantee its effectiveness. Your Administration can maximize the commission's impact in the following ways:

- The President will appoint 5 members of the 15-member body, 2 of whom will be selected from the general public (the other 3 are the Secretary of Health and Human Services (HHS), the Administrator of Veterans' Affairs, and the Secretary of Defense). These two appointees should be senior experts of national stature in areas of particular relevance to AIDS. They should not be chosen because they hold any particular political ideology.
- The commission will submit its reports to the President and to the appropriate committees of Congress. In addition, however, the chairman should have direct access to you. The work of the commission will have the greatest possible effect on policy if it is widely perceived that its chairman has the ear of the President. The President can endow the commission with sufficient national stature and credibility for its advice to influence all participants in the struggle against AIDS.
- The commission is required to report its recommendations 1 and 2 years after its constitution. Although the reports will identify needed action, the commission will be most valuable if it is also consulted on a continuing basis as policy questions arise within the Executive Branch.

2. Protect HIV-infected Persons from Discrimination

HIV transmission occurs through sexual contact, the use of contaminated needles or syringes, exposure to infected blood or blood products, transplantation of infected tissue or organs, and from mother to child either across the placenta or during delivery (and probably during breastfeeding). There is no

evidence that HIV is transmitted by casual contact or by insects. Therefore, there are no grounds for discriminating against persons with HIV infection or AIDS because of fears that they pose a health risk through casual contact in schools, in the workplace, in housing, or in customary social interchanges. However, such discrimination does exist, and fear of discrimination discourages some individuals at risk for infection from cooperating with voluntary testing programs, contact notification, and other potentially effective public health measures. Public health measures crucial in controlling the HIV epidemic depend on voluntary cooperation; for that cooperation to occur, people must believe that they will be protected from discrimination.

- The President should ask Congress to enact legislation designed to prevent discrimination on the basis of HIV infection or AIDS in both the public and private sectors.

3. Develop a Comprehensive Plan for Financing the Care of Those with HIV Infection and AIDS

The average lifetime medical expenses per AIDS patient in the United States, from diagnosis to death, are from $65,000 to $80,000. In 1986, estimated total direct costs for AIDS were approximately $1.64 billion—$1.1 billion for personal medical care and $542 million for nonpersonal expenses; this figure represents 0.4 percent of total U.S. health expenditures for 1986. By 1991, direct costs associated with AIDS are projected to be $10.8 billion and to account for approximately 1.5 percent of national health care expenditures. Although the proportion of total health care expenditures devoted to AIDS will continue to be small through 1991, in certain metropolitan areas the economic burden to the health care sector will be great. For instance, in San Francisco, AIDS patients are expected to occupy 12.4 percent of all medical/surgical hospital beds.

According to the Health Care Financing Administration, Medicaid provides health care coverage for approximately 40 percent of all patients with AIDS. Public hospitals in states with stringent Medicaid eligibility requirements are faced with growing numbers of uninsured AIDS patients; the result is that many public hospitals are incompletely reimbursed for the care they provide. Medicare currently covers only 1 percent of AIDS patients, in part because they often do not survive the required 24-month waiting period to qualify for benefits. Private health insurance may pay for a dwindling share of AIDS patients as more poor and nonworking persons become sick and because insurers are making plans to limit their exposure to financial risk.

Solutions to financing AIDS health care can reflect the pluralism of the current health care financing system. Elements of a comprehensive financing strategy could include: enabling HIV-infected persons to secure or maintain private insurance through insurer tax incentives and government subsidy of premiums; modifying existing state Medicaid programs to make them more uniform and more efficient; shortening or eliminating the 24-month waiting period for Medicare benefits; establishing state risk pools; and establishing an AIDS federal grant program to direct funds to the states on the basis of a formula that reflects individual states' AIDS caseloads and resources.

- The Secretary of HHS should develop an AIDS federal grant program to the states to ensure that AIDS patients and those with HIV-related conditions have access to appropriate and cost-effective care. This approach would offer some immediate financial relief to those hard-hit states and medical institutions that currently bear a disproportionate burden of AIDS care.
- Another immediate need is to remove financial barriers to drug therapies. The Secretary of HHS should require that all state medicaid programs reimburse for costly AIDS drugs once they have been approved for marketing or under the Food and Drug Administration's treatment investigational new drug mechanism.
- Piecemeal solutions to the problems of health care financing must not sidetrack the need for a more comprehensive scheme. Your Secretary of HHS should take the lead in developing a comprehensive national plan for delivering and financing care for needy HIV-infected and AIDS patients. The following principles should guide the development of such a financing strategy: (1) coverage from the time HIV infection is discovered, (2) consideration of relief for hard-hit communities, (3) shared responsibility between public and private sectors, and (4) payment mechanisms that encourage the most cost-effective types of care.

4. Initiate a Forceful Program for the Treatment of Substance Abuse and the Prevention of the Associated Spread of HIV

The gross inadequacy of efforts to reduce HIV transmission among intravenous (IV) drug abusers, when considered in relation to the scope and implications of such transmission, is the most serious deficiency in current efforts to control HIV infection in the United States. IV drug abusers are the second largest group of AIDS sufferers, and the most likely to transmit HIV to their heterosexual partners. Several actions are necessary.

- First, the Secretary of HHS should order a rapid, large-scale expansion of drug abuse treatment capacity to offer immediate access to all addicts who request treatment. Expansion is necessary in facilities that offer residential drug-free treatment, outpatient treatment, and methadone maintenance. Methadone maintenance, an effective therapy for some heroin addicts, does not treat cocaine addiction. Yet IV cocaine abuse is increasingly related to transmission of HIV infection. Research to find effective treatment for cocaine addiction is urgently needed.
- Second, innovative intervention programs must be begun to reach those IV drug abusers who are not in treatment. Former IV drug abusers, functioning as community health workers, can provide individual risk-reduction counseling; in addition, trials of sterile needle exchange programs, in which sterile needles and syringes are provided to drug abusers, should be implemented and evaluated.
- Finally, long-term drug abuse prevention strategies are needed that begin with teens and preteens. Research and evaluation are necessary to determine which prevention methods work best.

5. Institute Aggressive and Unambiguous Educational Programs and Evaluate Their Effects

Educational efforts to foster and sustain behavioral change are the only practical means now available to stem the spread of HIV infection. Information about the modes of HIV transmission must be conveyed in an understandable, yet scientifically accurate form. The message of AIDS education programs must also address sexual behavior and drug abuse, matters that are regarded by some as morally unsuitable for description in public health campaigns. Unsubstantiated concern that frank, straightforward educational programs can encourage IV drug abuse or sexual relations has stymied educational efforts. Explicit information on the risks associated with unsafe sex and drug abuse and the way those risks can be minimized does not promote or encourage such activities. Its sole function is to help people avoid an illness that endangers their lives and those of their sexual partners and children, and costs the nation billions of dollars.

- Government at all levels should continue to fund factual educational programs designed to foster behavioral change. This may mean supporting AIDS education efforts that contain explicit, practical, and perhaps graphic advice targeted at specific audiences about safer sexual practices and how to avoid the dangers of shared needles and syringes.

This is the approach followed in the United Kingdom and in other Western European countries.

- In addition, the Secretary of HHS should see that more studies are conducted to determine the effects of various types of educational campaigns on specific populations. For example, there have been few systematic assessments of the effect of AIDS education programs or media presentations on the behavior of heterosexuals (as opposed to the impact on their beliefs or understanding about the disease). It is also essential to develop effective methods for reaching school-age children, youth who are just becoming sexually active, and persons at risk for HIV infection within minority communities.

The urgency of the HIV epidemic warrants a multiplicity of educational efforts, including the use of paid advertising to convey all types of AIDS-prevention messages on television and in other media. A number of federal government entities, including the military, the postal service, Amtrak, and the U.S. Mint, currently spend more than $300 million yearly for advertising. Administrative restrictions from the Department of Health and Human Services have precluded the Centers for Disease Control (CDC) from paying for advertising in the past; the recently enacted AIDS Amendments of 1988 now allow the CDC to purchase advertising time.

- The Secretary of HHS should direct the CDC to purchase advertising for educational messages and should make certain that funds are supplied to do so.

6. Ensure that HIV Testing and Other Public Health Measures Are Employed Only When Their Purposes Are Clear and Their Results Productive

The ability to detect antibody to HIV has prompted various proposals for testing individuals and screening populations for evidence of HIV infection. However, these proposals must be assessed carefully to evaluate what they might add to interventions that are possible in the absence of testing. The President can encourage a level-headed approach to testing strategies by conveying the belief that HIV testing alone is not a panacea. Several considerations follow.

First, it is essential that the purpose of any proposed testing plan be clearly spelled out; test results should be linked to actions that achieve individual or public health objectives. For example, donated blood, tissue, organs, and semen can be tested, and infected material discarded, thereby preventing trans-

mission. This purpose is sound and has been achieved: the screening of blood for antibodies to HIV, combined with self-disqualification by potential donors at high risk for infection, has almost eliminated the transmission of HIV through blood and blood products. A common rationale for medical testing—to identify infected, asymptomatic persons so that they can be treated early—cannot be applied to HIV infection, since no therapy yet exists that prevents the progression of HIV infection to overt illness.

Another frequently cited purpose of testing, that knowledge of one's antibody status may encourage behavior change, is a hoped for but still unproven relation. In addition, it has been argued that uninfected persons can use the knowledge of others' test results to protect themselves from infection; or, in some situations (e.g., the military, jails, and other closed populations), authorities can intervene to protect uninfected persons by testing and then segregating infected persons. Extension of these strategies to the general population, however, is inappropriate and infeasible because 1 million or more people may be infected, the mean incubation period is 8 to 9 years, and the virus is not transmitted by casual contact. The testing of applicants for marriage licenses has also been tried, but such testing is costly, identifies very few infected individuals, and is not clear in its intent (if one of the applicants were infected, would marriage or pregnancy be prohibited?).

- At this time, the only mandatory screening appropriate for public health purposes is that of donated blood, tissue, and organs. Voluntary testing, however, will play an increasingly useful role against the spread of HIV infection. The Secretary of HHS should ensure that voluntary testing, combined with pretest and posttest counseling, is available to all those who may be at risk for exposure to HIV. For example, serologic testing and counseling should be extended immediately to all settings in which IV drug abusers are seen or treated.

The technical aspects of HIV testing must also be considered. Although the current tests for HIV antibody are highly accurate, there will inevitably be false-positive and false-negative results (and the proportion of positive test results that are false is largest when the test is applied to populations with a low prevalence of infection).

- The federal government should give more attention to establishing standards for laboratory proficiency in HIV antibody testing, setting criteria for interpreting assays, and instituting quality assurance procedures.

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Other public health measures should also be carefully considered for their potential effectiveness in controlling the spread of HIV and for their conformity with social values.

Voluntary contact notification, for instance, may be useful in preventing the spread of HIV infection. Contact notification programs allow local public health officials or physicians to inform the sexual or needle-sharing partners of HIV-infected individuals who are afraid, embarrassed, or unwilling to notify partners themselves. These programs are of greatest value when directed at those who otherwise could be unaware that they had risked infection.

Mandatory reporting of persons who test positive for HIV antibodies, on the other hand, should not be required at this time. In fact, the effect of mandatory reporting may be to discourage individuals from seeking voluntary testing, a cost that does not justify its potential benefit. For determining how many people in a population are infected, well-designed studies are more useful than random reporting of cases.

7. Bolster Efforts at Surveillance, Case Reporting, and the Gathering of Information About Risk Behavior

By November 1988, over 76,000 AIDS cases had been reported to the CDC. Of these, over 40,000 have died. An additional 10 to 20 percent of cases are believed to have been missed by the case surveillance system. The Public Health Service predicts that by the end of 1992, 365,000 cases of AIDS will have been diagnosed.

Estimates of the total number of persons infected with HIV are less certain. Methods used to estimate the number of currently infected persons rely on information that is itself uncertain, for example, the prevalence of infection in certain subgroups (e.g., homosexual men and IV drug abusers), the sizes of these subgroups, and the latency period between infection and the onset of AIDS.

It is essential to maintain reliable data on current AIDS cases, to refine estimates of the extent of current HIV infection, and to predict accurately future trends in the epidemic. Several actions will serve these ends:

- The Secretary of HHS should ensure that the CDC's personnel, space, and technical resources are adequate to the task of continuing epidemiological research and surveillance, including the development of mathematical models of the HIV epidemic.
- The Secretary should also see that adequate research support is provided to the social and behavioral sciences so that more can be learned about

sexual behavior, about IV drug abuse patterns, and about how to influence behavioral change.

8. Ensure that Biomedical Research Continues to Follow Fruitful Paths

Substantial progress has been made in defining the genetic structure of HIV and understanding how the virus replicates; less well understood, however, is how HIV compromises the human immune system and causes disease. Understanding the processes and consequences of HIV infection is crucial to the development of therapies and vaccines against HIV and AIDS. This understanding, in turn, is rooted in all basic research in the areas of cellular biology, virology, immunology, and genetics. For this reason, increasing the amount of funds devoted to AIDS at the expense of all other basic biomedical research is shortsighted.

- Funding for basic research in all areas of biology should remain strong rather than be reduced in favor of AIDS-targeted research.

Current knowledge of the HIV proteins and their functions offers several potential targets for rational drug design. The search for therapeutic agents must also encompass the screening of existing compounds for potential antiviral activity. Both of these approaches to drug development require organizational cooperation among government, the pharmaceutical industry, and academic health centers.

Once a drug appears to be a candidate substance for the treatment of HIV infection or AIDS, it begins the long journey toward licensure. The U.S. drug approval process, which is regulated by the Food and Drug Administration (FDA), is the most rigorous in the world; it generally involves tests in animals and then a three- or sometimes four-phase series of clinical (human) trials for safety and efficacy. Although the process has been criticized as slow and cumbersome, it has also been credited with protecting the American public from the harmful effects of inadequately tested drugs. In response to the AIDS crisis, FDA has moved to speed up some portions of its review and has established a category of investigational new drugs (IND) called the "treatment IND," which allows manufacturers to distribute a drug for use (if the drug meets certain criteria) while it is still under investigation. Zidovudine (AZT), which was approved in September 1986 under a prototype treatment IND mechanism, received the fastest evaluation that has ever occurred within the FDA. In addition, new FDA regulations will allow the approval and marketing of certain drugs after Phase II testing.

However, the diversion of FDA personnel necessary to approve zidovudine resulted in a backlog of applications in the FDA's Division of Anti-Infective Drug Products. As the number of applications for treatment IND status grows, these personnel problems may become more severe. At present, FDA is not a bottleneck in the availability of new drugs to treat HIV infection and AIDS. The paucity of new drugs is related more to shortcomings in the science of antiviral agents than to the drug approval process. However, as more promising new drugs are discovered or designed, FDA, without additional resources, could become an impediment to speedy availability.

- FDA's resources for new drug approval should be commensurate with the task. The need to borrow personnel from other parts of the agency should be relieved; the need for work space, which appears to be particularly acute, should also be addressed.

Although FDA has responded with ingenuity to hasten the availability of new drugs against HIV, a note of caution is warranted. The treatment INDs (and certainly the widespread use of unapproved drugs obtained here or abroad) could interfere with the ability to execute conclusive clinical trials because new experimental drugs will be available to patients earlier than in the past.

- In light of these concerns, the Secretary of HHS should direct the FDA to seek an outside evaluation of the treatment IND process and other new regulations designed to hasten drug approval or availability. This evaluation should take place after enough time has elapsed to determine whether new regulations have unanticipated consequences for any new drugs.

The urgency of the AIDS situation has brought the traditional scientific method for evaluating the effectiveness of treatment—randomized controlled clinical trials—under scrutiny. Criticism of this method grows in part from the frustration, fear, and anger of people with HIV infection, who may feel a lack of urgency in the drug development process. Yet, carefully controlled trials remain the fastest, most efficient way to determine what treatments work. Conducting well-designed trials from the beginning will benefit more patients, sooner, than any other approach. Poorly designed trials, or administering drugs without controls and "observing" the course of disease, can be inconclusive or draw incorrect conclusions. The widespread distribution of untested drugs makes it difficult to determine whether they are effective, especially if the benefits are real but small. The result of these approaches could include the continued prescribing of useless or harmful therapies.

Although the best designed clinical trial would enroll the fewest people needed to demonstrate drug effectiveness, many persons with HIV infection want to participate in clinical trials.

- The National Institutes of Health (NIH) should provide wider access to clinical trials by broadening their geographic base; by extending trials to previously untapped populations including women, IV drug abusers, and pediatric patients; and by testing all compounds that appear to have a possibility of effectiveness.

The prevention of HIV infection by vaccination continues to pose fundamental difficulties. Experiments with candidate vaccines in animals induce antibodies that fail to block subsequent HIV infection. These experimental results tend to mirror clinical observations of natural infection in patients, in which disease progresses despite the presence of antibodies and other immune responses. The advent of a licensed vaccine against HIV remains a distant prospect. Nonetheless, innovative research continues and may produce more promising results in the future.

In the meantime, FDA has approved human trials for two vaccine candidates. These tests, designed to assess the safety and immunogenicity of the vaccine candidates, were approved in the absence of proof of protective efficacy in animals, a generally accepted prerequisite to human vaccine trials.

- In the future, FDA should approve human trials for HIV vaccine candidates only when (1) protection against infection has been demonstrated in a suitable animal model or (2) the vaccine candidate rests on fundamental new knowledge of the relevant human response that cannot be adequately modeled in animals.
- In addition, NIH, CDC, and other relevant government agencies should begin now to plan for large-scale human efficacy trials of as yet undeveloped vaccines. Such trials are complex to design, and their results will be difficult to evaluate. Because the trials must enroll sufficiently large numbers of subjects at sufficiently high risk of infection, the sites for vaccine efficacy tests will most likely include African and other developing countries. A process should be agreed on for joint decision making among the countries involved; the World Health Organization is currently developing guidelines for the conduct of these trials.

The development of model systems, in which an animal infected with HIV or a similar animal virus shows the same symptoms and exhibits the same course of disease progression found in human AIDS patients, is essential to the campaign against the disease. Yet there is currently no such model. Chimpan-

zees and other primates are less perfect but nevertheless useful animal models, but they are in short supply for research purposes.

- Plans for breeding, conserving, and otherwise expanding the present stock of chimpanzees should be examined. This expansion may require increased funding. In addition, the development of a mouse (or other small animal) model for AIDS is of utmost importance. A promising development in this area is the transplantation of human fetal immune system elements into immunodeficient mice. As long as efforts to develop small animal models are carried out under safe laboratory conditions, further work in this area should be strongly supported.

Existing facilities are inadequate for further advances in research against HIV: very few laboratories are equipped to handle the virus safely.

- The director of NIH, in consultation with research scientists from within and without the institutes, should assess the need for and costs of new intramural and extramural facilities for AIDS research. This information should be forwarded to the Secretary of HHS and Congress for evaluation and subsequent action.

Federal appropriations for AIDS research have been growing steadily. At the present rate of increase, research funding will reach the goal (previously recommended by the Institute of Medicine and National Academy of Sciences) of $1 billion annually by 1990.

- When federal research expenditures for AIDS reach this figure, an assessment of the need for further increases should be made. It is important to ensure that other federal research programs are not penalized by a long-term disproportionate growth of the AIDS budget.

9. Recognize Our Special Responsibility in International Health Efforts to Control AIDS

The rationale for U.S. involvement in international AIDS activities is more broadly based than the protection of American troops and tourists. AIDS can destabilize the work forces and the economies of developing countries whose advancement has been aided by U.S. dollars. AIDS can also reverse the child survival figures in countries where our help only recently has improved infant and child survival. Finally, some countries of the world offer important

opportunities for collaborative AIDS research because they present varieties and prevalences of disease that do not exist in the United States.

- The United States has an additional responsibility to international health efforts to control AIDS because of our exceptional resources in public health specialists and biomedical scientists, the large number of infected persons in the United States, and our relative affluence.

American activities in international work against AIDS are conducted by many federal agencies. In addition, U.S. contributions to the WHO Global Programme on AIDS (which provides support to national AIDS control and prevention programs and conducts global AIDS surveillance and research) were $1 million in 1986, $5 million in 1987, and about $15 million in 1988. Your Administration should plan now to provide a substantial increase in resources over the next few decades to be devoted to international AIDS prevention and control, reaching $50 million annually by 1990. Funds will also be needed to ensure that today's predominantly educational methods for preventing HIV transmission can be supplemented with appropriate vaccines and drugs if and when they become available.

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Important as the above responses are, a further resource in the nation's efforts against AIDS is solely the provenance of the President—a resolve that the devastation caused by HIV infection will be prevented and its sufferers provided compassionate care, and an attitude that bespeaks the resolve.

TESTIMONY

on behalf of

NATIONAL ORGANIZATIONS RESPONDING TO AIDS (NORA)

submitted to

SENATOR EDWARD KENNEDY

COMMITTEE ON LABOR AND HUMAN RESOURCES

February 7, 1989

Mr. Chairman, members of the committee: the National Organizations Responding to AIDS (NORA) coalition welcomes this opportunity to testify before the committee at the beginning of the 101st Congress. AIDS has been described by the President as the number one public health priority for our nation, and while we believe this rhetoric has all the best intentions, it is essential to look beyond words and assess the adequacy of our national response to the this epidemic. Your committee's decision to highlight this issue through oversight hearing is a welcome signal to 125 national organizations represented by NORA which have made a commitment to working together on a competent and compassionate federal response.

Last year, the distinguished chairman and ranking minority member of this committee showed outstanding leadership in crafting and enacting the first authorizing legislation for our national fight against AIDS. Title II of Public Law 100-607, the Health Programs Extension Act of 1988, gives authority and guidance to federal efforts in research, prevention, and patient care, and shows that Congress regards this epidemic as a national crisis requiring the highest level of attention from the federal government.

The testimony submitted reflects the undersigned organizations perspectives on the current functioning level and ability of the Public Health Service AIDS programs as well as an analysis of whether current funding proposals contained within the FY 1990 budget proposals of both former president Reagan and President Bush can adequately cover the programs and services required.

This committee will soon hold confirmation hearings for both the Secretary-designate and the Assistant Secretary for Health-designate for HHS. We would appreciate the committee's attention to the qualifications that both candidates bring and how those experiences and knowledge will translate into effective administration and advocacy for the nation's AIDS programs. There will be few tasks that this committee will perform in the next few months in response to the challenges posed by AIDS that are more important than the confirmation and questioning of the appointees brought before you.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Beginning with the Office of the Assistant Secretary for Health (OASH), it is essential that this position be fully vested with the leadership and authority necessary to coordinate the nations response to AIDS. Clearly empowering that office and defining its relationship to other agencies must be high on the priority list for both the new Administration and the 101st Congress. Part of this leadership role should be to ensure that AIDS programs do not expand at the expense of other health programs and disease control efforts.

However, vesting that office with appropriate authority does not require consolidating the AIDS program and service dollars into a single account as has been recommended in the FY 1990 budget. It is our position that the Assistant Secretary is actively engaged in the budget process and therefore such a proposal will only add another bureaucratic level.

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) presently has an AIDS structure which designates an NIH - wide coordinator and staff responsible directly to the Director of NIH. The role of the AIDS coordinator is: public presentations, scientific coordination, budget preparation, and representation of NIH at Public Health Service meetings and activities.

While the framework that exists appears adequate, there are a number of functional concerns that still need to be addressed either through legislative mandate or agency policy changes. The prime concern is whether or not NIH has adequate staff to competently meet

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the mandates of the Congress and the promise of the agency's mission.

While NIH is recognized for working quite diligently on advancing scientific research, several factors have acted as impediments to the rapid implementation and expansion of critically needed research programs. The "AIDS Amendments of 1988" contained within P.L.100-607 dealt with a number of these impediments. Unfortunately, the FY 1990 budget does not contain the necessary dollars to implement the solutions already passed by Congress. Furthermore, the flexibility of NIH to fund research in order to meet emerging needs has been hamstrung by the Office of Management and Budget (OMB). The result of such bureaucratic intervention by OMB has been to compromise our nation's research effort. While the excellent work of NIH in basic biomedical research is acknowledged, a number of concerns exist about the lack of quality research, performed by NIH, in the equally important behavioral and social science research fields.

As with most of the PHS agencies, the lack of space and personnel has seriously restricted both AIDS program efforts, as well as simultaneously halting necessary work on other important scientific programs and research. In legislation passed by the 100th Congress, NIH was mandated to increase its in-patient and out-patient capacity as well as to expedite grant and contract review. However, at the present time OMB has placed a hiring freeze at the Clinical Center and throughout the NIH. Furthermore, the Congress has mandated improved access by traditionally underserved populations to community-based clinical trials, and we are concerned that these programs have not been adequately funded in the FY 1990 budget.

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) has the principal responsibility for expediting the approval of treatments for HIV-related disease. Currently it has a coordination system in place that is similar to the structure at NIH. While this system appears to adequately coordinate agency functions, the FDA still lacks critical resources to move promising AIDS therapies quickly to market. Furthermore, debate continues over how to best design regulatory policies in order to make new therapies available early to those with life-threatening illness.

The FDA has recently announced changes in its approval process aimed at approving new drug applications (NDAs) on the basis of phase 2 data, thus eliminating the several years that are normally required for more extensive phase 3 studies. While we welcome the responsiveness shown by these regulations, we are concerned that regulations not be seen as a substitute for aggressive use of existing regulations on treatment-IND (investigational new drug) protocols.

The new FDA procedures will work only if significant resources are committed to them. These procedures will multiply the time required to process IND applications by expert scientific staff, increase the need for expert staff and outside consultants, and require laboratory facilities for new research responsibilities. Compounding these problems is the dramatic increase in applications for new drugs and equipment, largely attributable to the AIDS epidemic. The Health Programs Act and the new FDA regulations also call for the FDA to actively solicit new applications.

At present, the FDA acknowledges serious problems with quality control, evaluation, staff, office space and technology. FDA suffers from a unique office space problem. At present, it occupies over eight different buildings which are geographically dispersed throughout the Washington, D.C. metropolitan area. As a result, the agency's AIDS activities are not all housed in one location. Although FY 1989 appropriations have been allocated for a consolidated AIDS building, it is not expected anytime in the near future. In the meantime,

FDA has plans for personnel to "desk share" the existing space on alternate days, and work out of their homes on the days no desk is available.

Compounding staff and space problems is the fact that the AIDS epidemic has dramatically increased the number of potential new drugs and equipment that the FDA is responsible for reviewing and perhaps approving. This dramatic increase in requests for review applications has necessitated an expansion of FDA staff with specific and highly technical backgrounds. The existing recruitment and retention problems of FDA are exacerbated by the time it takes to train scientists for these important jobs. The Commissioner of FDA has publicly complained about these problems yet the budget proposal submitted from FDA for FY 1990 was reduced by OMB by nearly $13 million.

Lastly, FDA is lacking an up-to-date communications system. A key component of the regulatory changes proposed by FDA includes communicating earlier in the approval process with manufacturers and working more closely with them throughout the research design and implementation phases. Current communications technology available at FDA is antiquated and insufficient to meet this new plan. It is our belief that the FDA approval time of treatment protocols and NDA's would be shortened if, in fact, the FDA had a state-of-the-art system that would enable it to communicate via computer with various applicants.

CENTERS FOR DISEASE CONTROL

The Centers for Disease Control (CDC) is perhaps regarded as the epicenter of AIDS prevention activities within our country. Their primary functions of surveillance, epidemiology and prevention are scattered among the various departments of CDC and are overseen by the Deputy Director for AIDS.

There is general satisfaction with the quality of information collected by the CDC under its surveillance program. However, many experts are eager to see more creative epidemiological studies, particularly among populations that are difficult to reach.

The prevention programs have more of a mixed record. They are diffused organizationally through several centers within the agency. Frequently it is difficult to pin point where activities are carried out, never mind how well the programs are working. For example, targeted minority outreach efforts are divided between the National AIDS Program and the Center for Prevention Services. Neither program is formally affiliated with the office of the Assistant Director of CDC for minority health.

As CDC's role expands to meet the challenges posed by HIV, it is important that the prevention efforts focusing on sexual transmission of HIV logically connect to its long-standing role in preventing sexually transmitted diseases (STD's). Currently STD prevention programs and HIV prevention programs are insufficiently integrated, even though both programs seek to modify behavior.

The FY 1990 Budget shortchanged the CDC and apparently seeks to freeze and reduce the availability of programs and services currently provided. For example, expansion of funding for community-based organizations is not possible under the current proposal, even though they are the key to successful prevention efforts. Funding to state and local governments for the AIDS control efforts, including HIV testing, will be level in FY 1990, despite an increasing caseload and expanded need.

Funds authorized by Congress and intended for CDC in P.L. 100-607 were specifically designed to implement effective prevention and education programs (including paid advertising), create several information hotlines, expand anonymous HIV testing and counseling and initiate new education programs for hard to reach populations. However

these funds are not accounted for in the FY 1990 budget proposal. Overall the CDC had requested almost twice the budget authority that it actually received within the FY 1990 budget request.

During two separate deliberations on AIDS education policy, the 100th Congress eliminated statutory language that previously had had a chilling effect on AIDS prevention programs. Although the new statutory language has been in effect for several months, CDC has not substantially altered their guidelines to reflect Congressional intent. The chilling effect of past restrictions will continue until grant applicants are informed of the new rules. In the meantime, many potentially effective HIV prevention strategies will go unproposed and thus unfunded and untried. This means new infections and eventual deaths that could have been prevented. CDC should take immediate steps to inform applicants of the new rules, alter their current erroneous guidelines, and encourage innovative approaches to AIDS prevention.

ALCOHOL DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

The Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) currently administers both HIV-related research and HIV-related mental health and substance abuse programs, although the future for the latter appears quite bleak at the moment. Over the course of the past eight years ADAMHA has increasingly divested itself from the delivery of services and has more aggressively sought to involve itself in the narrow field of neuroscience. There is virtually no disagreement that neuroscience is an important research endeavor. However, it should not proceed at the cost of social and behavioral research nor research aimed at evaluating effective service delivery.

Historically, the National Institute on Drug Abuse (NIDA) has managed the PHS response to the spread of the virus among individuals who use drugs. This lead responsibility was consistent with the relationship NIDA has developed with state substance abuse agencies, substance abuse professionals and the various communities of users themselves. ADAMHA's expertise and historical mission around substance abuse is critical in the design of prevention and treatment services for IV drug users infected with HIV or at risk of infection.

The reality of HIV is that the infection is spread through specific behaviors. As such, facilitating behavior change remains the best opportunity to prevent the spread of the virus. Despite recommendations from the President's Commission on the HIV Epidemic, the National Academy of Sciences and many other organizations, social and behavior research lags far behind other AIDS/HIV-related initiatives. The research that has been done, especially with relation to substance abuse and mental health services, lacks appropriate evaluation which renders it useless in helping construct new programs and services delivered throughout PHS.

ADAMHA's FY 1990 budget should adequately fund and staff the social and behavioral science research activities and research training programs authorized in the AIDS Amendments of 1988.

HEALTH RESOURCES SERVICES ADMINISTRATION

The Health Resources Services Administration (HRSA) has assumed the leadership in demonstrating alternative care models and providing professional training targeted at the AIDS crisis. Currently, HRSA's major AIDS activities and staff responsibilities are split between the Office of Special Projects and the Office of the Associate Administrator for AIDS. The AIDS administrator reports directly to the administrator of HRSA. The

responsibilities of the associate administrator entail a coordinating role, however, that position carries no authority over the individual programs or offices within HRSA. The director of the Office of Special Projects has authority over the demonstration grants currently underway for AIDS as well as responsibility for a number of other projects (e.g. organ transplants).

Currently, HRSA's AIDS grant activities cover five topical areas: services demonstration; education and training; AZT state subsidies; pediatric AIDS; and housing and facilities. There are a number of concerns that have been raised by experts regarding the coordination of these grants, the expertise of the staff administrating the grants, and the quality of program evaluation that is included within the grant awards. Overall, information generated through the demonstration projects have not been adequately evaluated and disseminated for use by other service organizations.

As HRSA continues to expand its scope of services to meet the growing needs of communities, attention must be paid to the allocation of resources. For example, as grants to low and moderate incidence communities are given priority, without additional resources, it is expected that high incidence communities currently receiving funds will find these grants reduced. If we are to truly move forward in assisting communities in an adequate response to the AIDS epidemic, additional resources to deal with emerging issues must be forthcoming.

HRSA's role as a communication point for health care delivery should be established immediately. Linkages to other programs within HHS, as well as to departments throughout the bureaucracy, could facilitate valuable information exchange on existing avenues for care that are either under-utilized or over-utilized. Exploring the various programs that have served traditional disability and special-needs populations could provide information on creative ways to finance community-based care as well as reveal serious gaps in health care and social services.

HRSA's traditional role in developing models of care could be expanded and enhanced through increased communication with AIDS service providers, state and local governments, reimbursement avenues and grant recipients. An active dialogue between the public and private sector, facilitated through HRSA, could substantially augment the availability and accessibility of quality care and services for persons with HIV infections and their families.

The FY 1990 budget excluded funding for some critical programs and activities expected to be carried out through HRSA. For example, the Congress authorized the spending of $100 million for providing grants to demonstrate effective home care services and for providing additional funding to early intervention and mental health programs, but these programs were not funded within the final budget proposal. This committee has heard testimony that the average cost for home and community-based AIDS care is about $80 a day, compared with an average of $800 a day for hospital care. In addition, initiatives aimed at increasing the participation of health care professionals in service delivery and programs to facilitate the participation of poor and minority communities in NIH sponsored community drug trials were not funded. Recent studies indicate that 40% of AIDS cases thus far, and an even greater proportion of new infections, occur in Black and Latino communities that already lack primary health care. These initiatives cannot begin too soon to address these needs.

Discrepancy between HRSA requests and OMB allocations reflects the nation's continued neglect of the care delivery issues and crisis associated with AIDS. For the first time in FY 1990, HRSA proposes to channel $11 million to the AIDS service activities of migrant and community health centers. With the expanding problem of HIV-related care in the general population, and particularly in the low income and minority communities, $11 million is but a start with much more needed in the future. The administration request for additional

care dollars in community and migrant health care centers indicates that HRSA will be unable to initiate any new programs in FY 1990 and will only be able to continue existing, underfunded programs.

Obviously this testimony does not deal with the complex and important issues related to health care and social service financing. Respecting the jurisdiction of this committee, we have presented an overview of the functional capacity of the Public Health Services in relationship to the AIDS epidemic.

Mr. Chairman, our AIDS agenda continues to grow with the exponential increase in the number of Americans infected with HIV. However, the resources committed by the Federal Government have not kept pace. Fully understanding the fiscal constraints our nation faces, the NORA coalition seeks to inform the Congress on the utilization of services, effective programs of prevention, education and care, as well as bureaucratic obstacles to providing necessary assistance. The investment in AIDS that this testimony outlines is one designed to minimize the long-term budgetary impact of AIDS. This overview provides you with some critical issues in the policy and funding arenas of PHS. We look forward to a continued partnership with this committee, the new administration and a concerned nation.

Sincerely,

AIDS Action Council
American Association for Counseling and Development
American Association for Marriage and Family Therapy
American Association of Sex Educators, Counselors and Therapists
American Association of University Affiliated Programs
American College Health Association
American Foundation for AIDS Research
American Jewish Committee
American Nurses' Association
American Psychological Association
American Public Health Association
American Red Cross
Child Welfare League of America
Disability Rights Education and Defense Fund, Inc.
Human Rights Campaign Fund
Legal Action Center
National AIDS Network
National Association for Home Care
National Association of Community Health Centers, Inc.
National Association of Counties
National Association of People with AIDS
National Association of Protection and Advocacy Systems
National Association of Public Hospitals
National Association of State Alcohol and Drug Abuse Directors
National Council on La Raza
National Gay and Lesbian Task Force
National P.T.A.
United Church Board for Homeland Ministries

National Organizations Responding to AIDS

January 17, 1989

Dear Senator:

In your consideration of the budget resolution for fiscal year 1990, the undersigned members of the National Organizations Responding to AIDS (NORA) coalition urge you to support at least $2 billion for the Public Health Service's AIDS activities. We are painfully aware of the tight fiscal constraints under which the fiscal 1990 budget will be constructed. Thus, we have limited our recommendation to the amounts requested by the agencies for fiscal year 1990 prior to OMB review, inspite of the fact that we support additional spending in certain areas.

We have designed our budget to minimize the long-term monetary impact of AIDS. If we do not invest today in the search for a treatment and cure, in the implementation of comprehensive prevention programs, and the development of cost-effective methods of care for people with HIV-related illnesses, our future health care costs will be tremendous. Indeed, tomorrow's Medicaid costs alone will be many times greater than today's "savings" should we choose not to adequately fund research and prevention activities in FY 1990.

We recommend the following levels of funding (as compared to the current fiscal year and the President's request):

Agency	FY89	FY90 (Pres.)	FY90 (NORA)
	(in millions of dollars)		
ADAMHA	175	218	229
CDC	382	474	602
FDA	65	57	71
HRSA	45	56	154
Indian HS		1	1
NIH	607	753	900
OASH	13	16	16
Contingency		25	
TOTAL	1,287	1,600	1,973+

a coalition convened by
AIDS ACTION COUNCIL
2033 M Street, N.W. • Suite 801 • Washington, D.C. 20036
(202) 293-2886 • FAX (202) 296-1292

Among the areas in critical need of the higher levels of funding indicated above are: expansion of outreach and prevention programs in minority communities (CDC); expedited review of applications for licensure and treatment INDs (FDA); expansion of clinical trials of experimental AIDS drugs, in particular of community-based trials in all populations affected by AIDS, including women, children and drug abusers (NIH); provision of quality care to persons in underserved areas and the development of innovative, cost-effective models of HIV-related care (HRSA); accelerated research into the neurological complications associated with HIV infection and into methods of behavior change critical to AIDS prevention (ADAMHA); expansion of drug abuse prevention and treatment programs (ADAMHA).

The levels of funding requested are also necessary if we are to begin implementing the programs authorized by Congress last year in the Omnibus Health legislation (P.L.100-607). The President's budget levels do not reflect the funding of these new or expanded programs. Similarly, the agency requests on which we are basing our own recommendation do not include funding P.L. 100-607. However, we believe the funding levels we are suggesting would at least give the appropriations committees sufficient flexibility to meet some of the new mandates. (Among P.L. 100-607's requirements that may not be funded because of the President's budget are: home and community based health care grants, additional beds for AIDS at NIH, expanded AIDS outpatient capacity at the NIH Clinical Center, creation of several information hotlines, expanded anonymous HIV testing, creation of several databanks regarding treatments and clinical trials, and expanded education activities for certain targeted groups.)

In supporting this level of funding for AIDS activities at PHS, we must state our view that increased AIDS funding should <u>not</u> occur at the expense of other critical activities at the PHS -- from biomedical and behavioral research to other disease prevention activities. We are deeply concerned that other health programs have once again been underfunded by the Office of Management and Budget. We urge the budget committee to compare carefully the discrepancies between the professional assessments of need made by the agencies and what the OMB has allowed.

We thank you for your long-standing support of the nation's fight against AIDS and look forward to working with you as the fiscal 1990 budget-making process gets underway.

Sincerely,

AIDS Action Council
American Association for Counseling and Development
American Association for Marriage and Family Therapy
American Association of University Affiliated Programs

American College Health Association
American Foundation for AIDS Research
American Home Economics Association
American Lung Association
American Nurses Association
American Psychiatric Association
American Psychological Association
American Public Health Association
American Red Cross
Association of Maternal and Child Health Programs
Association of Schools of Public Health
Association of State and Territorial Health Officials
Center for Population Options
Child Welfare League of America
Committee for Children
Chronic Fatigue Syndrome Information Institute, Inc.
City of New York
Disability Rights Education and Defense Fund, Inc.
Human Rights Campaign Fund
Hospice Association of America
National AIDS Network
National Association for Home Care
National Association of Community Health Centers, Inc.
National Association of People with AIDS
National Association of Protection and Advocacy Systems
National Association of Public Hospitals
National Association of Social Workers
National Association of State Alcohol and Drug Abuse Directors
National Council on La Raza
National Family Planning and Reproductive Health Association
National Gay and Lesbian Task Force
National Hospice Organization
National Leadership Coalition on AIDS
National Mental Health Association
National Minority AIDS Council
National Network of Runaway and Youth Services
National P.T.A.
National Puerto Rican Coalition
Planned Parenthood Federation of America
Union of American Hebrew Congregations
United Food and Commercial Workers International Union
United States Conference of Local Health Officers
United States Conference of Mayors

The CHAIRMAN. Thank you, Dr. Thier. I know you have to go, but I am glad that you are aware of the efforts we made for developing treatment and care outside of the traditional hospital setting, with the home health care program, and I too am hopeful that we will be able to receive some funding for that in this Congress.

Just one point. You have stressed the importance of education. How do you evaluate public service advertisement versus paid advertising? I know the Institute did a study of it, and I would be interested in what conclusions you have reached.

Dr. THIER. I think the general sense was that public service advertisements could have content which would be useful. The problem is that their ability to target audiences and to come on line at times that people would actually watch them, as opposed to simply waiting on line and getting whatever time they might get, such as two in the morning, dramatically reduces their impact; and that if we really think this is important enough, we ought to be willing to put some resources behind putting it in a form and at a time that the audience we want to see it will receive that message.

The CHAIRMAN. We do that, for example, with recruitment for the military, very effectively, so it is not an alien concept as a public policy issue; the real question is, as you stated earlier, whether we are going to make the real commitment necessary to be able to deal with it.

I have no further questions. I want to thank you very much. Your testimony is always enormously valuable to the committee, and we all have a great respect for the Institute.

Dr. THIER. Thank you very much, Mr. Chairman.

The CHAIRMAN. Dr. Matheny, we are pleased to welcome you. Dr. Matheny is the Associate Administrator for AIDS from the Health Resources and Services Administration. We will hear about the various AIDS projects and what important information the AIDS demonstrations have uncovered. In addition, we hope to look at the health care needs of people with AIDS and the role of home—and community-based care in meeting those needs.

STATEMENT OF DR. SAMUEL MATHENY, ASSOCIATE ADMINISTRATOR FOR AIDS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROCKVILLE, MD

Dr. MATHENY. Thank you, Senator.

I am pleased to appear before you today to describe some of the AIDS programs of the Health Resources and Services Administration. I have submitted longer testimony, so I am going just to briefly to summarize some of the aspects of our activities and our concerns about patient care and health care delivery.

Within our agency, we have the responsibility for programs which relate to patient care and health care delivery as well as health care professional training. In that regard, in 1987, under the direction of Assistant Secretary for Health Windom, we established the Intergovernmental Task Force on AIDS, of which I was Vice Chair and Dr. David Sundwall was the Chair. The focus of that task force was to look at the availability and appropriate delivery of AIDS services, as well as issues concerning continuity of care

and gaps in care and identification of how these services should be met.

We felt that this was an excellent way to bring a number of folks together to discuss with key Federal Government players how the State and local governments could participate in these decisions.

The recommendations of this task force have proven to be helpful in guiding the HRSA programs and establishing the guidelines about how the grant programs were developed.

I have also served as chair for the last couple of years of the Subgroup on Patient Care and Health Care Delivery of the Executive Task Force on AIDS in the Public Health Service. This group functions as a coordinative body for all activities conducted by the PHS agencies relating to health services for persons infected with HIV.

We participated in and developed the report which was recently published in Public Health Reports in January 1989, which in many ways reflected a lot of our current thinking about needs and issues around patient care and health care issues faced at the current time.

Since 1986, we have addressed the needs for AIDS through patient care activities and the following grant programs. Just to mention them briefly, we have Service Demonstration grants; regional Education and Training Centers for health care workers; and a Services Planning Program, which is a new activity I will talk a little bit more about later. We also have initiated grants for care for pediatric AIDS cases, and, in the last year, for renovation of intermediate and long-term care facilities.

The CHAIRMAN. On the issue of pediatric AIDS—and seeing my friend here, who is principal sponsor of the daycare initiative—I understand there is increasing demand for daycare in selected sitings. This is something that I was not as familiar with as I have become in the past few weeks. How are we going to be able to deal with that particular issue? We have daycare problems in any event, but these are presenting some very important and demanding situations.

Have you have come across that at all?

Dr. MATHENY. Yes, Senator, I think that is correct, and I think that the daycare issue is becoming an issue across the gamut of the ages of people infected with the disease. We feel that daycare programs even for adults have taken on a great deal of importance as well, but across all of these ages, daycare programs are going to become increasingly important.

We also have had grants for treatment drugs for AIDS, which I will go into a little bit more.

From 1986 through 1988, we spent $94.2 million for these programs. Our fiscal year 1989 budget is $55 million, and we have requested $56.4 million in the fiscal year 1990 budget submitted earlier this year.

The AIDS Service Demonstration program began in September of 1986, and the four cities to receive funds at that time were the cities with the highest incidence of AIDS in this country. We provided funds to those cities to try to do the following things: identify service needs and develop some strategies to meet these needs; to help integrate available community resources into some sort of a system of care; to work on developing case management activities;

and to attempt, by doing this, to reduce the costs of providing that care and provide some alternatives for hospitalization.

Or, to phrase it another way, I think what we could say we were attempting to develop coalitions in these cities as well as look at the comprehensiveness of services and to attempt to establish some form of a continuum of care.

These grants have totalled approximately $38 million through 1988. 21 metropolitan areas, SMSAs, throughout the United States have received these funds, and we will have an additional $14 million available in 1989 to expand and continue some of these.

The CHAIRMAN. Tell us what you find with regard to the availability of home health care services for people with AIDS.

Dr. MATHENY. Home health care is really a part of all of these programs. We have encouraged and insisted that home health be an integral part of the planning activities and of the development of health care services for delivery of care to HIV-infected people throughout all of these demonstration areas.

Home health care, we feel, is important to do in the context of not just home health by itself, but of planning for a larger comprehensiveness of services. Home health care really has to be supported by appropriate case management, for the provision of home care services, as well as home health care services, as well as, for instance, daycare and a total kind of health care delivery package.

I think that currently in the demonstration grants, probably about 16 percent of our funds are paying for home health care.

The CHAIRMAN. Have you done an evaluation or come up with the sort of model type of treatment services? Have you done an evaluation of what exists in different parts of the country? Would you be able to—perhaps not today—but could you supply us with, say, the half dozen best in the country according to your own evaluation—or do you do that kind of an assessment?

Dr. MATHENY. The first programs have been running for just a little over 2 years. We are in the process of evaluating the first four sites that were selected—New York, Los Angeles, San Francisco, and Miami. We should have that evaluation finished in March. This is a descriptive evaluation of what we feel has been successful and what some of the issues have been in formulating these demonstration programs.

The CHAIRMAN. We would be very interested if you would be good enough to share that with the committee. I think it would be very, very instructive to us in terms of trying to shape and fashion the services.

Dr. MATHENY. We would be happy to do that, Senator.

The CHAIRMAN. On the home health care, how available is that outside of the demonstration purposes? How available is it generally as you have been looking around the country?

Dr. MATHENY. I think it varies by locale. In some areas, I think it has become a real integral part of the services. In San Francisco, home health services have been an important component, largely sponsored through a number of volunteer organizations and supplemented by some of our grant activities as well as Medicaid and local fundraising.

In other parts of the United States, home health care has been less an alternative. This is, I think, due to local resources and local

organizations which have been able to develop home health care services.

In all the cases where we have had demonstration grants, though, this has been something that we really have encouraged very strongly, both because of an improvement of quality of care and also, we hope, development of less expensive alternatives.

The CHAIRMAN. That is certainly a major consideration—it is not the only one, but the savings are dramatic—isn't that true?

Dr. MATHENY. We tend to feel so at this time. It is difficult to be definitive, because there has been no definite study showing that home health by itself is actually less expensive, but one would tend to feel that this is probably the case.

The CHAIRMAN. Well, it would certainly appear given the cost of hospital rooms.

Have you done any study about what percentage of hospital space, say, in San Francisco or New York or Boston even, is now being utilized in terms of AIDS patients, and what the projections might be, given the Institute of Medicine's studies that indicate that the disease is progressing and moving at a reasonably predictable rate?

Dr. MATHENY. I would have to quote Ann Seitowski's study in San Francisco—I am not quoting verbatim, and I would have to supply more accurate data for the record—but it is my understanding that probably the one city that we will see affected the most by 1990 will be San Francisco. I think she predicted 12 percent of hospital beds in San Francisco would probably be utilized by AIDS patients. I think it will probably go up—if it is not 5 percent in New York, it probably will be soon, and will be about 9 percent or higher by 1990. So it is different in different cities, and it is obviously not standard throughout the country.

The CHAIRMAN. Okay. Continue, please.

Dr. MATHENY. We also will be initiating, with fiscal year 1989 funds, grants to communities that have not yet experienced large numbers of cases of HIV, to develop planning activities. We hope that we and they can benefit from the experiences and the problems that have occurred already in communities that have had a higher incidence of AIDS.

So we will be working with these communities and will be issuing grants for planning both for communities and some States that as yet have not had such a high impact of the epidemic.

We have had since 1987 grants totalling approximately $45 million to 50 States and 5 territories for treatment drugs for AIDS. This has been for the distribution of AZT. The grant funds could only have been used to pay for the cost of the drug, including a reasonable dispensing fee, and not for any administrative costs. Around 6,000 persons benefitted from the AIDS drug program through 1988.

Our pediatric AIDS demonstration project was an important new initiative that begin in 1988. Approximately $4.8 million was awarded in fiscal year 1988 to support 13 pediatric care models. I will say that it was not limited only to infants and children, but also to working with mothers as well as the increasingly large problem of the adolescents and the high risks that adolescents face.

This is not only for treatment but also for prevention and education.

Another $7.8 million has been appropriated for similar activities in 1989.

AIDS facility construction and renovation programs also began in 1988, to support construction of non-acute intermediate and long-term care facilities for AIDS patients; $6.7 million in Federal funds was awarded in 1988 to 20 projects in 10 States to support construction, the cost of which was actually $31.4 million. I think that the seed money awarded through these grants will support a lot larger effort on the parts of the grantees themselves.

In 1989, $3.9 million more is appropriated for continuation of this effort.

The CHAIRMAN. As you well know, that is enormously important. Having been around to some of those hospitals—Boston City Hospital has a very modest program—but it is really a tragedy when you see these pediatric AIDS units.

Senator Metzenbaum initiated a very modest proposal on it a little over a year ago. We are enormously interested, again, in finding out what is happening in this area and finding out what the nature of the need is.

I know there is an independent program out in Los Angeles which is quite effective, but again, having those kinds of evaluations and finding out how they are working and which ones are working well would again be enormously helpful to us.

Do you do evaluations on those?

Dr. MATHENY. Yes, we do. As I said, we will have the first descriptive evaluation finished in March. We are initiating a smaller evaluation, looking at total costs, both inpatient and outpatient costs, which will be undertaken, and we hope to have some results next year from that.

The CHAIRMAN. Good.

Dr. MATHENY. We also have been attempting to improve the education of health professionals through health care support services, providing continuing education, and working with health professionals on information and referral resources—referral to people who are experienced in the delivery of care to HIV-infected people. This is done through the regional Education and Training Centers. By September 1988, we had awarded $12 million and established 13 Education and Training Centers. These centers have a regional responsibility. All areas of the United States now have an Education and Training Center to work with the health professionals in their particular communities.

We have $15 million appropriated in 1989 to continue these activities and are attempting to concentrate even more on training for those people who are working in federally funded centers.

The emphasis has been on working with community primary care providers, incorporating strategies for trying to integrate the care and responsibility for care for managing HIV infection among all health professionals throughout the United States, not attempting to try to concentrate that care in a few centers, with a few health care professionals. We assume that this responsibility should be shared by everyone.

The CHAIRMAN. Do you work with public health personnel—for example, the issue of firefighters and police getting educated about how to deal with some of the health implications of AIDS—do you set up training programs for any of these?

Dr. MATHENY. Perhaps Dr. Noble might want to address that a little later. There are some specific activities in CDC, working with first-provider training, and we have been trying to integrate this as well in the Education and Training Centers program.

The CHAIRMAN. All right.

Dr. MATHENY. While we both have a strong interest in this, I think CDC has the greater activity.

The CHAIRMAN. I see. Okay.

Dr. MATHENY. Aside from the five grant programs that I have mentioned, I just might mention a couple of other activities that I think will be of interest.

Two other relevant grant programs are administered by HRSA—the Community Health Centers and the Migrant Health Centers. Because of the populations that these particular centers serve, HIV infection in the client population has been a major concern of their staffs. In many cases these centers are located in areas of very high incidence/prevalence of HIV infection. For the benefit of these centers, we have been working to provide special guidance on how to respond to the needs of patients. In addition, these centers are participating in seroprevalence studies. We also have been working with these centers, together with CDC, our Maternal and Child Health programs, and hemophilia treatment centers, to include risk reduction, education, and psychosocial counseling.

In addition, as part of the President's budget for 1990, we are anticipating further targeted activity for working with the Community Health Centers attempting to help them meet the needs for delivery of health care to HIV-infected people in these areas.

Through an interagency agreement and coordination with the National Institute on Drug Abuse, we also will be awarding grants aimed at facilitating the integration of care for substance abusers and patients with HIV infection. These awards will be made both to community-based health care organizations to expand both their drug treatment capacity and to drug treatment centers to expand their capacity to deliver primary care in their settings.

We anticipate that this will be very helpful in attempting to integrate the services and provide better comprehensive services to the drug-abusing HIV-infected population.

In conclusion, Mr. Chairman, I would like to emphasize that HRSA has benefitted from the participation of both the private sector and different levels of Government in our planning process, and we will continue to work very closely with States and local levels of Government and community-based organizations in the operation of our AIDS programs.

Thank you, and I would be glad to answer any questions.

[The prepared statement of Dr. Matheny follows:]

STATEMENT

BY

SAMUEL C. MATHENY, M.D., M.P.H.

ASSOCIATE ADMINISTRATOR FOR AIDS

HEALTH RESOURCES AND SERVICES ADMINISTRATION

BEFORE THE

SENATE LABOR AND HUMAN RESOURCES COMMITTEE

HEARING ON AIDS

February 7, 1989

I am pleased to appear before you today to describe the AIDS programs of the Health Resources and Services Administration (HRSA).

Within the Public Health Service (PHS), HRSA has responsibility for Federal AIDS programs relating to patient care and health services delivery, as well as health care professional training. In 1987, the Intragovernmental Task Force on AIDS Health Care Delivery was established. I served as vice chairman of this Task Force. The central focus of the Task Force was on the availability and appropriate delivery of AIDS services, the continuity of care, and the identification of major gaps in services. The Task Force proved to be an excellent forum for bringing together Federal health policy makers with key players in State and local government and the private sector. The work of the Task Force has proven to be particularly relevant to HRSA because many of the recommendations in the Final Report published in January, 1988, have served to guide the development of HRSA AIDS programs.

The Task Force recommendations focused on the gaps in the service delivery system and called for Federal support of State, local, and private action in the following areas:

- alternatives to hospitalization;
- intravenous drug abuse treatment programs;
- education and training of physicians and other health professionals;
- support services for pediatric and adult AIDS and HIV infected patients and their families;
- recognition of mental illness, psychological impairment, life style and drug abuse problems in the treatment of AIDS patients;
- mobilization of voluntary and private sector organizations; and
- financing mechanisms to cover the particular needs of AIDS patients.

I currently serve as chairman of the Subgroup on Patient Care/Health Care Delivery of the Public Health Service Executive Task Force on AIDS. The subgroup functions as the coordinative body for all activities conducted by the PHS agencies relating to health services for persons infected with HIV.

I also served as co-chairman of the workgroup on Patient Care/Health Care Needs of the Second Public Health Service AIDS Prevention and Control Conference held in June 1988. The purpose of the workgroup was to pull together individuals from within the

Department to discuss and help coordinate health care delivery issues generated by AIDS/HIV infection.

Since 1986, HRSA has addressed many of the needs for AIDS services through the following six grant programs.

- Service demonstration projects;
- HIV services planning program grants (new in FY 1989);
- Grants for treatment drugs for AIDS;
- The pediatric AIDS demonstration program;
- The intermediate and long term care facility construction and renovation program; and
- Regional education and training centers.

From 1986 through 1988, we spent $94.2 million for these programs; our Fiscal Year (FY) 1989 budget for AIDS programs is $55.1 million, and we requested $56.4 million for FY 1990 in the budget submitted earlier this year.

Now, I will briefly describe each of the HRSA AIDS grant programs.

AIDS Service Demonstration Projects

The purpose of the service demonstration projects is to support and facilitate the organization of HIV-related patient care systems which will:

- Identify service needs and develop strategies to meet them;
- Integrate available community resources into a system of care;
- Provide effective case management to ensure continuity of services; and
- Reduce the costs of providing medical services by providing alternatives to hospitalization.

Currently, demonstration grants totalling approximately $38 million through FY 1988 have been awarded in 21 metropolitan areas with the largest number of reported AIDS cases, and an additional $14 million is available in FY 1989 to continue these efforts.

Although grant monies may not be used to pay for inpatient care, funds may be used to pay for case management, outpatient medical care, and other related services, as well as costs associated

with developing a coordinated network of services. A comprehensive AIDS service delivery network would include hospital services; outpatient, physician or clinic services; home health care, subacute skilled nursing, in-home support services, mental health services and counseling; and other related services. The episodic nature of the AIDS illness and HIV infection creates the need for coordination of services across providers and the HRSA grants have provided both the stimulus and some of the financial support for service coordination.

The AIDS service demonstration grants have often provided the incentive needed to launch a coordinated local response to AIDS services delivery. Since their focus is on developing a network for the metropolitan area, the demonstration projects serve as a catalyst for collaboration among community-based organizations and city, county and State health departments that otherwise might not occur. The Federal grant has provided valuable leverage to attract private contributions as well as State, local, or private foundation grants.

HRSA demonstration grants have been a particularly important source of funds for community-based organizations, and, therefore, important to the efforts to increase access to social and support services for those infected with HIV and people with

AIDS. A special emphasis is placed on delivery of services outside the hospital to reduce the total cost of AIDS care, including efforts to increase the availability of home health services for AIDS patients.

Recently, HRSA conducted a case study descriptive evaluation of the four initial demonstration project grantees in New York, San Francisco, Los Angeles, and Miami. The study will provide us with additional insight into the organization and financing issues associated with the care of AIDS patients. We expect the results to be available approximately April 1, 1989.

HRSA awarded a second contract in FY 1988 to tabulate data on service utilization and costs in these four community-based service delivery systems. This is one of the few studies underway on the costs of outpatient and clinic services and the costs of social services and support services needed in the home by AIDS patients. The results of this second contract are anticipated in January, 1990.

Human Immunodeficiency Virus (HIV) Services Planning Program Grants

During the FY 1989 appropriations process the Congress expressed

concern regarding the need to plan for regional systems of care and support in those areas that have not yet experienced a large caseload of HIV-infected patients. These lower prevalence communities will be given an opportunity to apply for planning grants available for the first time in FY 1989. Approximately $3.8 million is available to support this effort. HRSA anticipates that the grants will average $150,000 each, and that some 25 entities will be assisted in FY 89. The Notice of Availability of Funds will be published soon and grants will be awarded in August, 1989. Public and private entities will be eligible to apply, including State and local governments and nonprofit and for profit organizations capable of developing coordinated plans for services for persons with AIDS within designated cities and States. The project period will be 1 year in length.

Grants for Treatment Drugs for AIDS

The Supplemental Appropriations Act for Fiscal Year 1987 included $30 million to be awarded in one-time grants to the States and territories to pay for a drug zidovudine (AZT), known by the trade name Retrovir. Individuals who are eligible for such drug reimbursement are those determined by their State to be low-income and whose AZT costs are not covered by the State Medicaid

program or other third-party payors. Each State's allotment was determined on the basis of the number of that State's AIDS patients as a proportion of the national total.

A second round of one-time grants was authorized by P.L. 100-436. In total, $15 million were awarded, $10 million in Federal funds and $5 million in private funds.

As of February 1, 1989, HRSA had awarded grants totalling approximately $45 million to 50 States and five territories. The grant funds could be used only to pay for the cost of the drug (including a reasonable dispensing fee) and not for any Federal or State administrative costs associated with the program. Approximately 6,000 persons benefited from the AIDS drug program during 1988.

Pediatric AIDS Demonstration

An important new initiative in 1988 was our pediatric AIDS demonstration grant program. Approximately $4.4 million was awarded in FY 1988 to support 13 pediatric care models, and another $7.9 million has been appropriated for similar activities in FY 1989.

The objectives of the projects are to (1) demonstrate effective ways to prevent HIV infection, especially through reduction of perinatal transmission, (2) develop community-based, family centered, coordinated services for infected infants and children, and (3) develop programs to reduce the spread of the HIV infection to vulnerable populations of young people. The demonstration projects are intended to serve as models for other communities and to identify the range of resources needed to provide appropriate health care to pediatric AIDS patients.

In 1987, HRSA sponsored the Surgeon General's workshop on pediatric AIDS. This workshop had a significant impact on the development of policy and information exchange on pediatric AIDS among the different levels of government and the private sector, and helped to establish the goals and priorities of the pediatric demonstration program. This next summer HRSA is planning a follow-up to the 1987 pediatric AIDS workshop in Los Angeles. In addition, HRSA will be sponsoring a series of conferences this year on the risk of HIV infection among adolescent youth.

AIDS Facility Construction/Renovation Program

Another new program in FY 1988 was the grant program to support construction of non-acute intermediate and long-term care

facilities for AIDS patients. $6.7 million in Federal funds was awarded to twenty projects in ten States to support construction or renovation of facilities for AIDS patients, the total construction costs for these facilities will be $31.4 million ($6.7 million in Federal funds, plus $24.7 million from other sources). In FY 1989 $3.9 million has been appropriated for this program. These grants may be used to (1) expand or modernize nursing homes and hospices or convert portions of hospitals to subacute care facilities for AIDS patients; (2) increase residential capacity for AIDS patients by converting existing housing to small scale facilities for residential and medical services; or (3) renovate facilities to supply the full spectrum of intermediate and long term care services needed by AIDS patients during various stages of the disease.

Education and Training Centers (ETCS)

A major responsibility of HRSA is to improve the education of health professionals in providing health care and support services to AIDS patients and to provide continuing education, information and referral resources to support practicing health professionals working with HIV infected people. This objective is met by supporting Regional Education and Training Centers (ETCs) to meet the needs of health professionals. These Centers

are affiliated with universities, research centers, and other institutions of higher education. By September 1988, $12 million had been awarded to establish 13 ETCs. $15 million is appropriated in FY 1989 to continue these activities. Each of the ETCs is expected to provide AIDS/HIV training in the counseling, diagnosis, and management of patients and their families. Community primary care providers (physicians, dentists, nurses, etc.) will be trained to incorporate strategies for HIV prevention into clinical practice and persons will be trained to serve as instructors in their local area.

The ETCs must demonstrate:

- Cost-effective training methods and techniques;
- Regionalized services;
- The use of existing AIDS hotlines, clearinghouses and Treatment Evaluation Units to enhance their programs;
- A plan for training health professionals who serve large numbers of minority patients;
- A strategy for incorporating the ETC curriculum into interdisciplinary course offerings of undergraduate and graduate medical education programs within their service areas;
- A plan for evaluating the effectiveness of the ETC; and

- Collaboration with Area Health Education Centers, community-based AIDS organizations, medical and health professions schools, medical societies, local hospitals, and other health professional organizations.

Aside from the 5 AIDS grant programs I have described, two other major grant programs administered by HRSA are the Community Health Centers (CHCs) and Migrant Health Centers (MHCs). Because of the populations that these centers primarily serve, HIV infection is a major concern. For the benefit of these centers, HRSA has prepared and distributed special guidance on how to respond to the needs of AIDS patients. Furthermore, to estimate the extent of the HIV infection among the patient population of the centers, eight MHCs are participating in the CDC national seroprevalence study. Knowing the infection rate at the centers will be particularly helpful as we develop the comprehensive training program for staff in the CHCs and MHCs as part of the work of the ETCs.

Other Activities

Under an interagency agreement between HRSA and CDC, the maternal and child health program supports AIDS prevention activities in hemophilia treatment centers including risk reduction, education and psychosocial counseling.

Through an interagency agreement with the National Institute on Drug Abuse, we will be awarding grants to community-based health care organizations to expand drug abuse treatment capacity by integrating primary health care services and intravenous drug abuse treatment.

Thank you very much. I will be pleased to answer any questions you may have.

The CHAIRMAN. One feature of our legislation calls for home- and community-based care for people with AIDS. We had a block grant program to try and develop services where we do not see the services available, or where there is no system for reimbursement of those things.

Is that something that you have an opinion about? Would that be useful or helpful—without getting into the dollar figures and all the rest—what can you tell us about that type of program?

Dr. MATHENY. I would speak from the Patient Care Subgroup report that was published as part of the Public Health Service "Charlottesville Report" on that. We believe that home care be given an appropriate amount of attention and concern. Speaking in general terms, we have been very, very concerned about emphasizing this quite strongly among the grant programs we currently have. Anything that we can do, I think, to encourage that development, encourage participation in home care, is going to be an important aspect of trying to reduce costs and also to improve the quality of care.

The CHAIRMAN. Okay.

Senator Dodd.

Senator DODD. You mentioned the pediatric AIDS, and the chairman is correct; I have a strong interest in that and the connection between--the percentage, I guess, of the total AIDS population now is 20 percent that comes from the IV drug users. I guess the connection now has been pretty successfully made that 80 percent of the HIV-infected children are born to parents either with AIDS or at risk of getting full-blown AIDS disease.

You hear about these "boarder" children, and the chairman is right—Senator Metzenbaum has put some modest amounts of money to deal with that—you talk about these treatment programs, home care, community-based programs. To what extent are children being considered? I should preface the question, I guess, by asking whether or not you see that population continuing to grow, the infant population.

Dr. MATHENY. Perhaps Dr. Noble might want to add something to this, but I think there is no question that there is going to continue to be a disproportionate share of the AIDS problem associated with IV drug abuse—the mode of transmission through IV drug use and through being sexual partners of IV drug users.

Senator DODD. Given the fact that a lot of these children are being left in these hospitals, isn't that correct—I mean, they just walk away.

Dr. MATHENY. There is a significant problem in certain areas with that.

Senator DODD. So you do not have an extended family, or others—these children are pretty much just being abandoned.

Dr. MATHENY. We do have a significant problem of abandoned babies or "boarder" babies in several of the institutions.

Senator DODD. To what extent are your community-based or home care-based programs designed in some way to deal with this growing phenomenon?

Dr. MATHENY. Actually, both our service demonstration programs and our pediatric programs are aimed specifically at trying to work with these children. Instead of creating a whole new

system of care, what we really are attempting to do is to supplement and add to the current social services system or home care or to case management activities, but target these to the "boarder" baby issue. The other problem is that in many cases, there will be several infected members of the same family, so it may not be an "abandoned" child as much as that the child may not have any well parent who can assume the responsibility for care.

Senator DODD. Yes, I understand.

Dr. MATHENY. So it is a double issue. But several of our programs, in Rhode Island, in Massachusetts, in New York and in Miami, have been aimed specifically at trying to supplement activities, provide placement for children, and work with the social services programs to help with that.

Senator DODD. To what extent do we have educational programs for the foster care programs, for instance, to educate people as to what the risks are and so forth with taking on one of these children?

Dr. MATHENY. We have been attempting, with both the pediatric demonstration projects and the service demonstrations. Obviously, other activity sponsored by the HHS Office of Human Development Services also have been addressing these issues. But it has been an important concern of ours, including concern about appropriate education of the care provider. That has been a component of most of the pediatric demonstration programs where this has been the focus of attention.

Senator DODD. To follow up on what Senator Kennedy was asking you earlier, are you evaluating those programs specifically with regard to infants, to children?

Dr. MATHENY. Those programs are just in the first year of funding, and that evaluation is being planned at this time, but it has not been completed.

Senator DODD. I would be interested, Mr. Chairman, in that particular aspect of it. We may find a program that has shortcomings in other areas but, with regard to children, is particularly successful for some reason. So if you could kind of give us an independent evaluation of that, it might be helpful to us.

The CHAIRMAN. Why don't we write to the agency and ask them to consider that as they are doing some of the reviews. We will write and ask for that.

Senator DODD. I realize Gary Noble is up next, but I was just interested in to what extent do these community-based programs address this.

Dr. MATHENY. We also will be having a major pediatric conference and a follow-up to the Surgeon General's Workshop on Pediatric AIDS in September in Los Angeles, and I think those issues are going to be even more carefully addressed when we look at the recommendations of the Workshop of 2 years ago and of the Secretary's Work Group on Pediatric AIDS to see how those could be further carried out.

Senator DODD. Thank you very much, Doctor.

The CHAIRMAN. I would just mention that we had a family that provided foster care for seven of these children in Boston—just a remarkable willingness of a family to reach out. It is enormously impressive, I think, under any set of circumstances. So I do not

think any of us minimize the complexity in dealing with that, with children, but it is extraordinary that there are individuals who are willing to help in this way.

Thank you very much, Dr. Matheny. We know that you have been pinch hitting here today, and you did a very fine job, with very helpful testimony.

Dr. MATHENY. Thank you, Mr. Chairman.

[Additional material supplied for the record follows:]

1-26-89 LA Times

AIDS Patient Costs in L.A. Higher Than S.F.

By VICTOR F. ZONANA, *Times Staff Writer*

SAN FRANCISCO—The state Medi-Cal program spent about twice as much money per AIDS patient in Los Angeles last year as in San Francisco, according to a report issued Wednesday by the California Department of Health Services.

Shorter hospital stays, made possible by the Northern California city's extensive system of hospices and home health care, accounted for most of the difference. Daily hospital charges were also 15% less in San Francisco.

All told, Medi-Cal expenditures per AIDS patient per month were $2,953 in Los Angeles, compared to $1,514 in San Francisco, and the average hospital stay was 13.3 days in Los Angeles and 9.5 days in San Francisco.

"The message here is that the economic burden of AIDS can be significantly reduced by aggressively pursuing alternatives to in-patient hospital care," said Dr. Kenneth W. Kizer, director of the Department of Health Services, in an interview.

Medi-Cal paid the health-care costs for 33% of the state's AIDS patients last year, up from 27% in 1986 and 19% in 1983. Medi-Cal's AIDS-related expenditures have kept pace, rising to $42.8 million in the current fiscal year. They are expected to climb to $56.4 million next year.

Please see MEDI-CAL, Page 8

1-26-89 LA Times

MEDI-CAL: Expenditure on AIDS

Continued from Page 3

Despite the hefty tab, the report indicated that AIDS costs won't overwhelm the state, as some have feared. "You can't say that AIDS is going to break the bank, or bankrupt the [Medi-Cal] system," said Kizer, noting that the state will spend a total of $6.5 billion on the program this year.

He acknowledged, however, that the epidemic has severely strained certain regions and institutions, particularly public hospitals in Los Angeles and San Francisco.

And while the epidemic will continue to take a disproportionate toll on San Francisco, that city will likely account for a declining percentage of the state's AIDS cases in the future.

San Francisco accounted for 43% of the state's new cases in 1982 but will drop to 26% in 1990, according to the report. Meanwhile, Los Angeles' share of the caseload will rise from 34% to 38%, and all other areas of the state will go from 23% of new cases to 36%.

"This is a statewide issue," Kizer said. "Over time, there is no community in California that will not be touched by AIDS in a very personal way."

The Medi-Cal report was presented to a meeting here of the California AIDS Leadership Committee, a statewide group developing a comprehensive approach to combatting the disease. Kizer is co-chair of the committee.

Since the first cases of acquired immune deficiency syndrome were reported in 1981, about one-fourth of all cases reported in the United States have been from California.

Group Urges Doctors to Fight Malnutrition in AIDS Patients

By GINA KOLATA

Aggressive efforts to improve nutrition, including intravenous feeding and other medical intervention when necessary, could greatly improve the quality of life and possibly extend the lives of AIDS patients, a study group said today.

"Malnutrition in AIDS is common, severe, and progressive," said Dr. Donald P. Kotler, a panel member from St. Luke's-Roosevelt Hospital Center in New York. Starvation is a major contributing factor in the deaths of many AIDS patients, Dr. Kotler said at a news conference.

Guidelines Published

The 11-member group of government, academic, and hospital experts, headed by Dr. Myron Winick, a nutrition specialist at Columbia University in New York, developed guidelines for health professionals that are published in the January-February issue of Nutrition. It also wrote a pamphlet for AIDS patients for distribution nationally, through organizations that provide support for people infected with the AIDS virus.

Most patients who have AIDS are malnourished, although the reasons are varied, Dr. Winick said. Some cannot eat because they feel nauseated. Others have sores in their mouths that make eating painful, or diarrhea or infections that make it difficult to absorb food. Still others have infections, like tuberculosis, that speed up and derange their metabolisms. Even some drugs taken by AIDS patients can lead to malnutrition or vitamin deficiencies.

Yet, Dr. Kotler said, most doctors do not pay enough attention to malnutrition in their AIDS patients. The exceptions, he said, are private doctors in cities like New York who treat large numbers of AIDS patients. "There is a fair degree of nihilism and cynicism in caregivers who do not have a lot of contact with AIDS patients," he said.

"Is nutritional support in hospitals adequate? The answer is clearly no," Dr. Winick said.

Teaching of Patients Suggested

The panel recommended that AIDS patients be taught and encouraged to eat as much as they can, eating small, frequent meals if they are nauseated and drinking nutritional supplements available at drugstores.

When AIDS patients cannot eat, they should be fed through nasal tubes that they can insert themselves, or intravenously, the panel said.

Dr. Kotler described how nutritional therapy helped a 6-foot 2-inch AIDS patient who was so wasted from starvation that he weighed just 120 pounds and was too weak to get out of bed. The man was hospitalized while his disease was quiescent, was fed intravenously and gained 45 pounds. This allowed him to return home to his family, where he lived for the last six months of his life, before dying of a rapidly progressing dementia.

The panel was careful to say that the main proven benefit of nutritional therapy was to improve the quality of patients' lives, not necessarily to save their lives. Even though the panel members suspect that patients who are well nourished will live longer and their immune systems will function better, "this has not been proved," Dr. Winick said.

In the end, "We think there's a certain point where nutritional support does not work," said Dr. Jeffrey Norton of the National Institutes of Health in Bethesda, Md.

The key issue is "to better the patients while they have AIDS," Dr. Winick said.

Fad Diets Not Recommended

The group also said that people infected with the AIDS virus, but not yet ill, should avoid fad diets, like macrobiotic diets, which have not been shown to be beneficial and which can lead to nutritional deficiencies. They should instead have their nutritional status assessed, eat well-balanced diets, and maintain their weight to build up their nutritional reserves before they have to contend with the disease.

The group received a grant from Norwich Eaton Pharmaceuticals, a subsidiary of the Procter & Gamble Company. Norwich Eaton makes a nutrition formula that can be used in AIDS patients with bowel troubles. But the panel refrained from recommending any particular nutritional products.

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Where Will We Put Them All?

Will AIDS force city hospitals to collapse, or can we reshape health services?

By 1991, AIDS will have sent 31,000 New Yorkers to early graves. Some 12,000 more will be struggling with this treacherous disease; another 200,000 may carry the virus around like a silent time bomb. Not only must we learn to [illegible] with the enormous number of people [illegible]m AIDS, but we must also help those w[illegible] be living — however briefly — with it.

So far, the city has done a poor job. Just look at the overcrowded emergency rooms, the growing number of abandoned infants born with the virus, the 2,000 or more with AIDS who are homeless. *How will we care for them?*

Public hospitals are staggering under the load. Eleven municipal hospitals house only 16 percent of the medical beds here, yet they care for more than one-third of the AIDS patients. Unless this trend is reversed, warns Paul Moore, chief of AIDS initiatives at the Health and Hospitals Corporation, the public hospital system will become "an AIDS system."

That can affect every New Yorker. Need your appendix out? Sorry, no available bed. A friend injured in a car crash? Standing room only in ERs. Sure, shortages existed before most people had even heard of the HIV virus. But the AIDS epidemic has exacerbated the crunch by forcing a flood of young people who wouldn't otherwise be using medical services to swamp the system at an explosive rate. The need is so great that Mayor Edward Koch used part of his meeting with President-elect George Bush last week to plead for help in setting up nursing homes for AIDS sufferers.

Adding hospital beds is not the only answer (even if it were financially feasible, which it's not). Rather we need *non*hospital alternatives — nursing homes, at-home care, long-term residences, hospices. On any given day, as many as 80 AIDS patients are needlessly kept in city hospital beds — each costing $800 a day — because they have nowhere else to go. The hospital stay for AIDS patients here is on average twice as long as it is in San Francisco.

To get people out of the hospital who don't need to be there, the city must create a "continuum of care": appropriate care for patients *in the community*, perhaps even in the same building, at all different levels of their illness. Some AIDS patients can get along with minimal services; others only need care intermittently. Though rare, examples of model residences for people with AIDS (PWAs) exist: Bailey House, where homeless AIDS patients live under the eyes of a round-the-clock staff. Or the Village Nursing Home's day treatment center for about 70 PWAs who still live at home. Or buildings run by the PWA Coalition in Dallas for people like "Mary" who has AIDS and two kids, one of whom is infected.

City Hall must consult with neighborhoods, but they, in turn, must accept AIDS homes — or risk having them forced on them, as the mayor and governor have threatened.

Yet bricks and mortar aren't enough. Support services — like home-care attendants or rental assistance — which enable people to stay at home can save millions by keeping people out of hospitals and shelters.

Here's the problem. While the AIDS virus has been making progress, the bureaucracy has not. So it's much easier to get public money for an $800-a-day hospital bed than for a $100-a-day group residence. Washington bears a lot of the blame, since it restricts Medicaid and welfare payments. Still, the state does have some control over R & R — rules and regulations. Some changes have trickled out of the Cuomo administration, but why isn't it setting higher reimbursement rates for ambulatory services, or for construction of AIDS nursing homes? While the state did increase payments to "AIDS Care Centers," many hospitals haven't been able to meet the state's unrelentingly rigid rules. Some officials doubt that the state's five-year plan on AIDS, due out this month, will suggest enough specific R & R changes.

Meanwhile, the city should extend a hand to the thousands who are infected with the virus and show some symptoms, but don't fit the clinical definition of AIDS and thus fall between the cracks. Individuals like "John" who has AIDS-related complex (ARC). He was discharged from a psychiatric ward to a homeless shelter, a practice forbidden for those diagnosed as having AIDS. Besides, some doctors believe early care for ARC may help stave off more serious and costly health problems.

The private sector, for its part, can develop alternative care models, which might later be eligible for public money — something the New York City AIDS Fund is attempting. But while a lot of groups may know what to do, they don't know how to do it. That's where technical assistance comes in. The Gay Men's Health Crisis, for instance, evolved from a six-person group to a globally recognized, $10 million organization in just a few years. A Rockefeller Brothers grant for strategic planning helped it manage the growth.

And there's more. Staffing shortages have meant that only 18 of the 500 extra hospital beds already approved have opened. So innovative recruitment strategies are critical. So is coordination between City Hall and Albany. Eight years into the epidemic, there's still no official responsible for services to PWAs on the city or state level. City Health Commissioner Stephen Joseph may be the mayor's nominal adviser on AIDS, but he has no real control over services provided by other agencies.

AIDS has not only underscored existing problems in our health care system, but created new ones. Ultimately, prevention is the only sure way to reduce this crunch. But in the meantime, we'll need a network of out-of-hospital care and some courageous decisions by New Yorkers in public office and communities.

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1-16-89 LA Times

Positive Step on AIDS

The preliminary passage of a Los Angeles County anti-discrimination ordinance, protecting those with the human immunodeficiency virus (HIV) that causes AIDS, is a constructive step. It would put into effect the implementation of a key recommendation of the Presidential Commission on the HIV Epidemic.

Municipal Judge Rand Schrader, vice chairman of the county AIDS Commission, urged passage of the ordinance because it makes "clear and unequivocal" the position of the Board of Supervisors, just as the Los Angeles City Council made its position clear in 1985 with the adoption of a municipal anti-discrimination law. He was right. And making that clear in the county is of particular importance because the county ranks second in the nation in the incidence of AIDS.

The vote was by the narrowest possible margin, however, with Supervisors Pete Schabarum and Mike Antonovich voting in opposition. The majority of three was made up of Supervisors Deane Dana, Kenneth Hahn and Ed Edelman.

There were signs that the opposition was based on misunderstandings. Antonovich argued that it would duplicate federal and state laws. He had perhaps forgotten that the radical right forced out of federal legislation proposals for broad protections against discrimination and that Gov. George Deukmejian had vetoed state legislation last October that would have extended protections to those who test positive to the virus but who may not yet have AIDS. Protection of those with the virus but without symptoms of the disease is an important provision of the county ordinance. Furthermore, it was argued that this would be a costly venture when, in fact, it will not be because it provides only for recourse to the civil courts or the county dispute-resolution program in the event of violations.

The community will be well served if the supervisors can now move ahead on other critical questions related to the AIDS pandemic. Until now, there has not been majority support for more candid informational programs targeted on high-risk populations. And only Edelman of the five supervisors thus far has supported the proposal of the county AIDS Commission for a campaign directed at intravenous drug users that would include the distribution of bleach for cleaning needles and of condoms to encourage safer sex. These programs have been proved effective in other communities, and delays in their implementation only raise the risk of an accelerated spread of the infection.

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PRESS RELEASE

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For Immediate Release

Contact: Bill Halamadaris
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AIDS EPIDEMIC REACHES SMALL TOWN AMERICA

A new national survey indicates that the first wave of the AIDS epidemic has swept through urban America and spilled over into the heartland.

The Foundation for Hospice and Homecare, a non-profit group in Washington, DC, surveyed 7,000 hospices and home care agencies around the country. Tabulated results show the following:

- AIDS is no longer just an urban problem.
- Community agencies are becoming progressively involved in caring for AIDS patients.
- Reimbursement and funding are major problems.
- The "4 Hs" of the AIDS population no longer apply.
- Hospices and home care agencies are picking up the burden of care.

Of the 1,205 hospices and home care agencies that responded, 551 are already providing services to persons with AIDS. Only 130 of these agencies classify themselves as "urban." More than 100 are located in rural communities (113) and the largest number call their location "mixed" (*i.e.*, 262 small town or suburban).

Although hospitals often provide acute care for AIDS patients and nursing homes infrequently provide long term care, more and more hospices and home health care agencies, based in the community, are becoming involved. As the incidence of AIDS cases has risen over the past five years, so too has the number of agencies caring for persons with AIDS.

When asked what the Foundation for Hospice and Homecare can do to help, two-thirds said "find funding." Written comments from around the country explain the problem: Often, there is a "lack of funds available for private duty home care for indigent AIDS patients" (Richmond, VA). Even when they have private insurance, persons with AIDS may require "more home health aide time than insurance will cover" (Dover, DE).

But private insurance is not the only difficulty. "Currently, it takes two years to qualify [*i.e.*, for Medicaid] if the patient has property or assets, or 45 days if he is eligible at the time of

application" (Petersburg, VA). Other respondents also suggest "make patients eligible for Medicaid sooner" (Tucson, AZ) and "develop better government-sponsored funding for care" (Racine, WI).

In the early days of the epidemic, public health officials designated "4 Hs" to describe groups of people most likely to get AIDS: homosexuals, heroin users, hemophiliacs, and Haitians. Home care agencies report that 11% of their AIDS patients are over age 65 and that 5% are under age 18. Already, four of every 25 persons with AIDS no longer fit the traditional groupings.

"Despite differences in geography, type, auspice and experience, the survey points out one basic similarity: hospice and home care agencies are providing humane alternatives to institutionalization," asserts former US Senator Frank Moss, Chairman of the Foundation Board.

Both hospital-based and free standing agencies provide the same types of services. The most common are nursing (88%); social work (61%); home infusion therapy (56%); physical therapy (56%); homemaker-home health aide (49%); and counseling, both pastoral and psychological (28% each).

The survey also indicates that "compassion is more important than cash," says Jan Bchara, Executive Assistant at the Foundation for Hospice and Homecare, who conducted the study. Although 654 agencies reported no experience yet with AIDS, 98% said they were willing to help. About nine out of ten (92%) have not yet had any referrals. Out of every 100 respondents, 98 say disincentives are not the issue. Lack of reimbursement, limited capacity, legal concerns, fear of infection, or fear of impact on agency do not worry them. In this group, 291 are rural agencies and 215 are located in small towns or suburbs.

"The statistics indicate hospice and homecare providers are picking up the burden of care," says Senator Moss. "Even those agencies who are not now serving AIDS patients expressed an overwhelming willingness--92%--to do so."

Among agencies with experience, 20% provided care without receiving any reimbursement. The average portion of the bill that went unpaid was 46%. Primary sources of reimbursement include private insurance (338 agencies--61%); state government (265--48%); Federal government (166--30%); local and county government (43/44--7% each). One-fifth of the agencies received support from their local communities.

Caregivers in local communitites can continue to fight the epidemic, said an administrator in a small Pennsylvania town: "Home care people could serve as primary sources of knowledge at the grass roots level. We are out here, face to face with the population."

HOME HEALTH CARE FACT SHEET

Home health agency: A public or private organization that provides nursing and other therapeutic services in the home.

Hospice: Philosophy of helping people live fully and independently until they die; team approach provides palliative (not curative) care to patient and family; often not a free-standing building but a group of services; hospices may be based in hospitals, communities, voluntary agencies, etc.

History (until 1965): Visiting nurse associations and governmental public health agencies are the oldest types of home health care organizations. Until 1965, when Medicare was enacted, they were the most numerous. The first modern hospice was established in London in 1967; Connecticut Hospice, the first in the US, opened in 1971. There are about 1,800 US hospices.

Medicare: Federal program to provide health services to persons over 65. Requires that "conditions for participation," be met, e.g., agencies must provide more than one service. About half of all home care agencies are certified to receive Medicare reimbursement. *Certification does not measure quality.* Medicare spent $2.91 billion for home health care in 1987. The average cost per visit: $60.

Number of Agencies: According to estimates of the National Association for Home Care, there are almost 11,000 agencies (10,848) in the USA; 53.5% are Medicare-certified.

Types of Agencies: In general, there are two types of home health care agencies, hospital-based (a regular department of the hospital) and free standing.

Auspices: Designates sponsorship, method of financing, and type of organizational control.

Voluntary--Visiting Nurse Associations; based in the community; not for profit. By 1886, in Boston, Buffalo, New York, and Philadelphia, nurses cared for patients at home, and taught family members hygiene and techniques.

Official--governmental; part of state, county or city department of public health; supported by taxes. Los Angeles County provided first public health nursing services in 1898.

For Profit--proprietary; often a subsidiary of a pharmaceutical (e.g.,Upjohn), hospital chain (e.g., Beverly Enterprises), or agency chain (e.g., Kelly). Rapid growth from passage of Medicare in 1965 to the present.

Private Non-Profit (PNP)--Fill need where there are no public health or visiting nurse associations; community-based; local Board of Directors; may solicit grants and contributions.

Clients: Home health care agencies provide services to all age groups and fulfill many different needs.

Infants--premature; birth defects; cared for at home; often dependent on respirators and other "hi tech" equipment.

Children--chronically ill; don't need hospitalization; skilled and support care provided.

Young adults--accidents, especially head and spinal cord injuries.

Adults--those who live with various disabilities and chronic illnesses.

Older adults--including the "frail elderly."

Foundation for Hospice and Homecare: National non-profit organization which operates its own programs to improve the continuum of health care for the disadvantaged, the disabled and the debilitated of all ages. Foundation activities include researching health care issues, accrediting home care agencies, publishing training and consumer materials, and recognizing distinguished examples of caregiving.

14:46 NATL ASSN: HOMECARE

THE NEW YORK TIMES, FRIDAY, NOVEMBER 20, 1987

SAVINGS ENVISIONED IN HOME AIDS CARE

Health Officials Say Broader Coverage Could Cut Costs of Treating Many Cases

Special to The New York Times

ATLANTA, Nov. 19 — The cost of caring for some AIDS patients could be reduced to less than $100 a day from about $800 a day if public and private health insurance plans would pay for home care of AIDS patients, health care officials say.

The average cost of care for an AIDS patient in a municipal hospital is about $800 a day, according to James M. Foster, a member of the San Francisco Health Commission. But Mr. Foster noted that a program operated by the Visiting Nurse Service of New York calculated its cost per patient at $81.40 a day.

"The problem with most of our insurance plans is that they were set up to cover the costs of hospitalization," said Phyllis Kraemer, president of AMBI Medical Management Systems, who was director of a two-day conference on home care of AIDS patients that ended here Wednesday. The conference for public health officials and private businesses involved in health care was sponsored by AMBI, a division of the McKesson Corporation, which distributes medical supplies.

"Doctors who are finding out that AIDS care will not be paid for at home will put patients into the hospital just to get things covered," Mrs. Kraemer said.

Dr. John C. Bartlett, director of AIDS Care Service at Johns Hopkins Hospital in Baltimore, said, "Private insurance companies are struggling to find more ways to avoid AIDS patients due to the high cost of care, and they are becoming more effective in doing so."

Not all AIDS patients can be treated at home, and most require hospitalization at some point in their illness. But Dr. Bartlett said AIDS patients required hospitalization an average of 2.4 times in the year between diagnosis and death. The average length of stay for each of those visits was 13.4 days, but "our impression is that the availability of a chronic care facilities would permit a reduction in the average length of stay from 13 days to 8 days, or possibly even less," Dr. Bartlett said.

Still, problems with public and private health insurance are not the only barriers to the care of AIDS patients outside of hospitals, health care officials at the conference said. There is a shortage of trained specialists in infectious diseases who could treat AIDS patients at home and a shortage of group care facilities for AIDS patients.

There is only one chronic care facility in Maryland that will accept AIDS patients, Dr. Bartlett said, and that has only five beds for AIDS patients and a continuous waiting list of 15 to 20.

But in other parts of the country, notably San Francisco, the situation is different.

"It is apparent that the costs of patient care from diagnosis to death are lower in San Francisco than in any other major city with large numbers of AIDS patients and where relevant data is available," he said. "The average length of hospital stay per patient is lower in San Francisco than in New York, Houston, Miami or Los Angeles, for instance."

Mr. Foster said part of the difference might be attributed to the higher proportion of gay men among the San Francisco victims and the relatively lower number of intravenous drug users, whose treatment usually is more costly. The drug users, several studies have indicated, are more likely to have other health problems as well as AIDS.

In addition, he said, "there is little doubt that the extensive system of support groups plays a large role in reducing the overall costs per patient in San Francisco." The drug users, in contrast, frequently have no place to go outside of the hospital while suffering from the disease.

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Excerpted fr(he Washington Post, Sun. January 31, 1988

San Francisco Curbs Cost, Trauma of AIDS

By Michael Abramowitz
Washington Post Staff Writer

SAN FRANCISCO—Soon after he was diagnosed last June, Jeff Shannon, a 32-year-old photographer living in New York, got a crash course in the harsh economics of AIDS.

Shannon had no health insurance, was earning less than $15,000 a year and was already, as he put it, "barely scratching along." Facing the prospect of thousands of dollars in medical bills, not to mention supporting himself at a time when he likely would be unable to keep working, Shannon concluded he couldn't stay in New York.

Today Shannon lives in San Francisco. He gives a quarter of his $538 monthly Social Security disability check to the Shanti project, a private social service agency that provides a group house for him and three other AIDS patients. He gets basic medical care at the AIDS clinic run by the University of California at San Francisco. The city pays for an hour with a psychiatrist each week, and another private group helps pay his utility bills.

"I knew that I could find a support network in San Francisco," Shannon said. "I could actually create a life style out here that would allow me to survive. That's why I came to San Francisco."

With the country's highest per capita incidence of acquired immune deficiency syndrome, the city of San Francisco has experienced more than its share of misery and death in the past six years. But adversity has brought a more positive distinction: a reputation for having developed perhaps the most humane, cost-effective system of caring for AIDS patients in the country.

In response to the AIDS epidemic, San Francisco has dramatically expanded new, low-cost alternatives to hospitalization, such as hospice and home care. The city has established a network of community groups and volunteers to cook, clean and provide emotional counseling and financial advice, among other support services that make these alternatives possible. And AIDS has revived compassion and other feelings that intense competition and a "bottom-line" mentality in much of the health care industry have eclipsed in recent years.

In many cases, AIDS only accelerated steps that already were under way—both in San Francisco and throughout the country—to create a better way to care for chronically ill patients. The result is an integrated system of inpatient, outpatient and community care that not only saves money but has drawn praise for easing the worst ravages of AIDS.

Since 1982, the average length of time AIDS patients stay in San Francisco hospitals has declined from roughly 18 days to 11 days, according to Philip Lee, president of the city's health commission. The figure is considerably lower than the lengths reported in most other major cities—for instance, more than 20 days in New York, Boston and Philadelphia and 16 days here in Washington.

This lower level of hospitalization has led to sharply lower costs per AIDS case. Researchers here have estimated that it now costs about $40,000 to treat AIDS patients from diagnosis to death in San Francisco, compared with a national average that has been calculated at more than $100,000 in various studies.

* * *

"AIDS is essentially an outpatient disease," said Dr. Donald Abrams, codirector of the AIDS division at San Francisco General, the city's public hospital, whose Ward 86 has become a huge outpatient clinic for AIDS patients. Noting that he was once disposed to hospitalize at the first sign of pneumocystis pneumonia, another common AIDS infection, Abrams said he is "more inclined to want people at home. The more people can stay at home, the more it increases quality of life."

"Early in the epidemic, patients tended to die in the intensive care unit on respirators. Doctors tried to pull out all the stops, and people died pretty inhumane deaths," said Dr. Jerome Schofferman, medical director of the city's major hospice. "But as more and more people saw friends die, they decided, why don't we let them die at home."

Often, it is the patients who insist they be able to receive treatment at home.

John Petuya, a retired mortgage banker was diagnosed with AIDS in 1986, shortly after returning from a vacation in Europe. Before his death last month at 47 years old, Petuya and Don Sheppard, who lived with him for 18 years, talked at length about fighting the disease on home ground—their yellow stucco house in the San Francisco suburb of Hayward.

Though the disease forced Petuya into the hospital twice, for the most part he was able to remain at home, despite a host of complications ranging from diarrhea, dizziness and dementia to pneumonia and a potentially blinding eye disease called CMV retinitis. A home nursing agency delivered Petuya's medications weekly, while Sheppard tended to his personal needs.

"I was scared, and I talked to Don and we discussed the burden," Petuya said. "It really wasn't a burden for him. I didn't want to go to the hospital. I wanted to be at home with Don and have Don take care of me."

For an hour a day, five days a week, Sheppard would attach intravenous tubing to a hat rack next to Petuya's bed and administer the required dosage of ganciclovir, an experimental drug to treat Petuya's retinitis. Twice a week, he drew blood for testing by a local hospital, which in turn sent the results to Petuya's physician, William Owen, one of San Francisco's most prominent AIDS doctors. Once a month, Sheppard, who also is a retired mortgage banker, drove Petuya an hour into the city for a checkup.

Owen was initially skeptical about the arrangement, but gradually became convinced because of his complete trust in Sheppard, who devoted virtually his whole day to caring for Petuya—from cooking and cleaning to ensuring that the catheter offering a direct line into his blood stream was kept clean.

"In the past, much of this would have required hospitalization," Owen said before Petuya died. "But I have a lot of confidence in Don's ability to take my orders, and I think we'll be able to get through this."

Looking back, Sheppard has no regrets.

"The treatment he got was the best he could have possibly received . . . ," Sheppard said. "He wanted to be at home. I wanted him to be at home. It just worked better at home."

Home Care Is Much Cheaper

The cost of home care can be as much as 75 percent less than the $800 to $1,000 it costs to be in the hospital for a day. As AIDS has mushroomed in San Francisco, doctors have detected much more willingness on the part of insurers to pay for different types of care, even when it is not formally part of a patient's benefits package.

Many AIDS patients exhaust their private insurance during the course of the illness and are forced onto the rolls of Medicaid, the federal-state insurance program for the poor, which covers roughly 12 percent of the entire population but an estimated 40 percent of all AIDS patients. Too sick to work, many AIDS patients quickly run through their savings.

It is a process that Petuya learned all too well; his insurance ran out in August and he was forced to "spend down" most of his assets to reach Medicaid eligibility limits. But while he could rely on housing and support from Sheppard, hundreds of other people with AIDS here turn to the services offered by a variety of private agencies in the city. It is the existence of these support services that doctors say gives them the confidence to discharge their patients from the hospital earlier.

Perhaps the best-known support group is the Shanti project, an organization founded in 1974 to deal with the problems of the dying and that has focused on AIDS exclusively since 1983. Shanti officials estimate that more than 80 percent of AIDS patients in the city [illegible] approach the group for help.

Shanti's services are varied. The project's residence program maintains 12 houses, and the 47 people with AIDS who live in them are asked to contribute up to one-quarter of their income as rent. Shanti volunteers help AIDS patients with cooking, cleaning and shopping, and drive them to medical appointments. Counselors work on a one-to-one basis with any AIDS patient in need of emotional support.

"We encourage people to let their feelings out," said Grey Day, Shanti's community relations director. "Whatever they are, we validate them. We are a nonjudgmental organization."

While the group's administrative staff and $7.2 million budget have increased sharply within the past five years, Shanti continues to rely on a cadre of volunteers trained in issues of death and dying and committed to at least eight hours of work a week. Shanti has more than 700 volunteers, who in the last year provided nearly 200,000 hours of unpaid service that Chris Sandoval, assistant director, estimates would cost $8 million annually on the open market.

* * *

"The system thus far has been able to respond, yet we're at a point where unless more resources are made available, we're not going to be able to cope with the epidemic in two years," said Lee of the Health Commission. "I don't want to cry wolf, but we're in a crisis situation."

Without increased federal and state funding, officials say, spending on AIDS will start cutting into other health care needs, such as spending for the homeless, the mentally ill or pregnant women. "We're not a very big city. It's not a very big tax base," said David Werdegar, director of the city Department of Public Health. "If the city had to continue to do all of these AIDS programs out of its own pocket, it couldn't do it."

But too few dollars may be the least of the city's worries. Another more troubling question is whether the city's medical and volunteer staff, already stretched thin by the epidemic, can sustain the effort.

Phil Sowa, executive director of San Francisco General, has seen staff burnout first-hand. On any given day, almost 40 AIDS patients are in General, taking up roughly one-quarter of the hospital's medical-surgical beds. Some of the nurses and doctors who have worked by choice in Unit 5A, the inpatient unit for AIDS patients, have been there since the unit opened in 1983. "We've reached a point of saturation," Sowa said.

"You can only go so far with the resources we have," he said. "Many of the people dealing with this epidemic have voluntarily provided their services. Many of the people are gay. Many of the people have seen multiple losses of loved ones and friends. People just get really tired of this and ask when is it going to end.

"We built a model to respond to the epidemic. Now the epidemic is driving

1.

Mr. Chairman, Let me begin by defining the purposes of the Stewart B. McKinney Foundation, Inc. They are to provide shelter, relief, support and assistance to poor, needy and indigent individuals with serious illnesses.

We are concentrating our efforts at this time on providing funds to residential programs for Homeless People With AIDS (P.W.A.'s). By providing these homes, we are removing people from the streets, the shelters and in many cases from hospitals. Many P.W.A.'s no longer need medical care, but are allowed to remain in the hospitals until housing is found. Our houses give them a place, a home to live in, in dignity,- and please understand- many are healthy enough to return to a job, but they are homeless due to discrimination, thus losing their jobs, their homes and their insurance benefits.

The Stewart B. McKinney Residences are limited to approximately five unrelated persons per single family dwelling in order to provide the true meaning of living within a family environment, and to allow them to positively participate and take charge of their lives with the help of health care professionals who restore their sense of hope, helpfulness and dignity.

These model McKinney Residences do not provide medical or convalescent care. All day to day services are provided by off-site agencies such as the Visiting Nurse Association (V.N.A.), Meals on Wheels, Volunteer Transport Services, and the Volunteer Buddy Program which are there to be utilized by any citizen in need.

In turn, these services are coordinated by an off-site paid service coordinator employed by the agency our Foundation funds, who is responsible for the day to day operation of the Residence Program. Without these off-site services, and our program these Residences could not exist.

Although residents are ambulatory, a requirement of residency, treatment for some opportunistic infections will require Chronic Maintenance Therapy, i.e. :

1. For C.M.V. (Cytomegalovirus) the drug most commonly used is Gancyclovir, which must be monitored by a professional, is administered approximately five times per week.

2. Cryptococcal Meningitis, the drug Amphotericin B is administered three times per week.

All treatments can be followed in-home, arranged by the service coordinator with a local V.N.A. representative or similar professional.

Mr. Chairman, the face of AIDS is changing. The virus is spreading most rapidly among the poor, the Black and Hispanic communities, and most importantly, the I.V. drug users. More drug treatment centers are desperately needed, for today the waiting period for entry can be upward of six months or more.

As the numbers of people infected with the virus escalates so must the numbers of people in the Health Care Field grow. The cost of new drug treatment centers along with the training of caregivers combined with the medical expenses are staggering. The private sector cannot take on the burden alone. State and Federal dollars are desperately needed.

Monies are also needed for case-workers (bi-lingual), as many P.W.A.'s do not know what government monies are available to them nor how to apply. This would enable quicker access to Title 19, Section 8, and Social Security. Many P.W.A.'s have died waiting for their benefits to come through.

Another point I would like to make has to do with the physicians. Those doctors who are treating P.W.A.'s on entitlements are reluctant to do so, as their reimbursements are so low and long in coming- if at all.
As an example a private physician charges from $50.00 to $75.00 for a routine or follow-up office visit. For those patients on entitlements, they receive $18.00 to $20.00. A routine office visit lasts from 15 minutes to a half hour, however, the P.W.A's needs are far greater and time spent with them is upward of one hour. This is not cost effective. Equitable reimbursements must be made in order to encourage more doctors to treat the ever growing number of P.W.A.'s on entitlements.

The words and statistics all read very familiarly, but with each passing report they seem a little more numbing and far too impersonal. According to a report issued by the Connecticut Department of Health Services last April, the number of identified AIDS cases jumped from 602 to 719 during the first four months of 1988, an increase of almost 20%. By the end of 1991, there will have been 2,900 cases of AIDS in Connecticut. Still other estimates place the number of H.I.V.-infected persons at about 20,000 to 25,000.

While these trends are unquestionably disturbing, the numbers alone do not begin to tell the story. Though not large in comparison to neighboring New York, these figures remain significant for several important reasons. First, they represent an unusually diverse population - different from New York and the nation as a whole. Approximately 50% are I.V. drug users (active addicts plus addicts under treatment). Consequently, the Connecticut AIDS population is considerably heterosexual and minority, mostly urban and indigent, with a growing number of women and children. This latter category includes prostitutes, out-of-school youth, and children of addicts. While the state's overall numbers do include many gay and bisexual men, even within these categories there are men who have sex with other men but do not identify themselves as a part of the traditionally gay community. They too represent a non-traditional and hard-to-reach population.

A second and equally disturbing revelation is the extent to which this diverse H.I.V.-infected population consists of persons who have limited or no access to medical care and experimental drug programs. Even worse, most have almost no close contact or positive relationships with the health care giving-community. Far too many feel shunned and alienated-isolated by poverty, geography, limited information, and minimal community understanding or support. Even where medical facilities exist, many of the state's AIDS patients simply lack reliable or regular transportation to take them to treatment centers.

In contrast there are segments of the H.I.V.-infected population (mostly white and middle-income individuals) who are turning increasingly to New York City or Boston for private care, especially with regard to experimental drug programs. As a result, Connecticut finds itself moving de facto toward a highly uneven and biased system of health care for its AIDS patients: those with connections and resources go out of state for treatment and support, while a growing percentage of indigent, minority, female and young AIDS patients remain in-state but find the necessary help and hope lacking.

Mr. Chairman, I hope I have been of help. Thank you for affording me the opportunity of speaking to you today.

Lucie C. McKinney

Chairman of the Board
Stewart B. McKinney Foundation, Inc.

The CHAIRMAN. We will hear next from Dr. Gary Noble, the Deputy Director for the AIDS Program at CDC. We are pleased to have you here.

Along with many other tasks, the Centers for Disease Control is charged with responsibility for implementing this Nation's AIDS education program. While research efforts continue, prevention is our only vaccine. Today, we hope to hear about the AIDS education projects in operation at the CDC and the impact of each, and whether the level of effort is adequate to meet the challenge.

We look forward to you testimony, Dr. Noble.

STATEMENT OF DR. GARY NOBLE, DEPUTY DIRECTOR FOR AIDS PROGRAM, CENTERS FOR DISEASE CONTROL, ATLANTA, GA

Dr. NOBLE. Thank you, Senator.

As Director of the AIDS programs at the CDC, I am pleased to represent CDC in discussing our comprehensive information/education efforts to assist States, localities and private groups to prevent HIV infection.

I will make my remarks short, since time is late.

As of January 2, 1989, 32,311 cases of AIDS were reported for 1988, which is a 57 percent increase over the number of cases reported in the previous year. Of the 1,375 children reported with AIDS since 1981, 583 cases were recorded during the past year, or a 77 percent increase over 1987.

The black population accounted for 26 percent of the total cumulative adult cases and 52 percent of the pediatric cases. Hispanics accounted for 15 percent of reported cumulative adult cases and 23 percent of pediatric cases. Although these two groups comprise only 20 percent of the Nation's population, they account for 41 percent of the adult cases and 75 percent of pediatric cases.

The strategy to control the spread of HIV infection is influenced by several factors. Most importantly, spread of the virus results from a few individual behaviors which, when altered, can prevent or reduce the possibility of transmission. HIV infection represents the first modern infectious disease causing significant morbidity and mortality for which health promotion alone is the major intervention tool.

The only method available to us to contain the epidemic is to convince people to avoid personal behaviors that could put them in contact with HIV.

A major portion of our budget for fiscal year 1989—$100 million, or one-quarter of our budget—supports counseling, testing, and partner notification. As you heard from Dr. Young concerning aerosolized pentamidine, we feel that the early diagnosis of HIV infection takes on increased urgency in light of recent information that aerosolized pentamidine given to asymptomatic HIV-infected individuals with a low CD4 cell count can reduce the risk of pneumocystis pneumonia.

Because HIV infection has affected minority populations disproportionately, CDC recognizes the critical need for increased efforts to reach these minority populations. In August of 1988, CDC Director Dr. James Mason appointed an Assistant Director for Minority Health. In November of last year, the position of Special Assistant

for Minority Policy Coordination was created in my office. We also will be expanding our existing strong collaboration with the Office of Minority Health in the Office of the Assistant Secretary for Health.

Our total fiscal year 1989 authorization for minority programs is $30 million, and requests for fiscal year 1990 are over $47 million for minority populations. In addition, much of our total program effort also reaches minority populations.

Approximately one out of every five Americans diagnosed with AIDS is between the ages of 20 and 29. Given an average incubation period of about seven years between the time of first infection with HIV and the diagnosis of AIDS, some portion of those in the 20- to 29-year age group diagnosed with AIDS were certainly infected as teenagers. More than 45 million students are enrolled in grades K through 12, and an additional 12 million students are enrolled in colleges and universities. Thus, of the total population in the United States, about one in four is in school or in college.

In fiscal year 1988, nearly $30 million was devoted to preventing HIV infection in school and college-aged youth; in fiscal year 1989, $35.7 million was appropriated, and $42.6 million is requested for fiscal year 1990.

CDC's program to reach this age group is composed of six integrated operating systems to enable schools and other agencies that serve youth to implement programs that can help young people avoid HIV infection and other important health programs.

Just to point out some of the problems that face us with adolescents, sexual behaviors that may lead to HIV infection are the cause of about 2.5 million cases of STD's—sexually transmitted diseases—annually, and about 800,000 unintended pregnancies in adolescents occur each year.

In the area of general information for the public, CDC launched the first phase of the national information campaign in October 1987. Three phases of the campaign have now entered the media channels, and the fourth phase, "Parents and Youth," will be released in April of 1989. Broadcast advertisers' report data generated by trained editors who review magnetic tapes of broadcast activity by national and selected local network cable and radio stations indicate that the "America Responds to AIDS" campaign became the dominant public service campaign in the Nation soon after it was launched in October 1987. The campaign has received more than $23 million of free air time during its first 14 months of activity, which ended November 30, 1988.

The CHAIRMAN. The GAO study says that 90 percent of the ads were shown during non-prime time, with 56 percent during fringe time. Is that about what your own assessment is, or did you not dispute that?

Dr. NOBLE. We have no reason to dispute that. The time at which the public service announcements are shown is of concern to us, but, as I will get to in a minute, knowledge in the general public is surprisingly high. May I come back to that?

The CHAIRMAN. Yes.

Dr. NOBLE. During fiscal year 1988, the hotline, which also serves the hearing-impaired, handled over 2 million calls—a volume of

calls five times larger than any health hotline service has ever received previously.

The National AIDS Clearinghouse in turn distributed an average of more than one million publications on HIV infection per week during its first year of operation.

Indicators of our effectiveness in informing the general pub[l]: are provided by the National Health Interview Survey, which is a cross-sectional household survey of the adult civilian population. From this survey, we know that knowledge levels about the actual transmission routes for HIV are extremely high, as I mentioned.

For example, 95 percent of American adults believe that the virus is very likely to be transmitted through sharing needles for drug use with an infected person.

The CHAIRMAN. What is the level of misconceptions?

Dr. NOBLE. Misconceptions concerning insects, toilet seats, and the likelihood that you can get HIV infection from blood transfusion remain at about 50 percent for those kinds of questions. So there is a problem with some of the misinformation.

The CHAIRMAN. Previously, you were talking about the hotline. Various options are currently being explored for implementing the professional hotline. What are those types of options?

Dr. NOBLE. Well, the Office of the Assistant Secretary for Health has begun to look at these options. One of the options that we think is viable is to take the existing hotline, which is run under contract with American Social Health Association, and expand that; that is a very viable option because it uses an ongoing very effective program. It would have to be expanded to be able to answer calls from professionals.

The CHAIRMAN. What is the principal inhibition? Is it resources?

Dr. NOBLE. It would take, obviously, more resources, yes.

The CHAIRMAN. Of what dimension? I mean, are you talking $5 million, or $10 million, or $50 million?

Dr. NOBLE. I think we will have to provide that. I am not sure that we have a firm figure.

The CHAIRMAN. Just generally; could you provide that for us?

Dr. NOBLE. Yes.

The most recent data we have from the National Health Interview Survey for the months of May through August 1988 indicate that an average of 85 percent of adults surveyed could recall seeing a public service announcement about AIDS on television in each of the four months surveyed.

Although the survey questionnaire did not ask for aggregate data for the total of PSA's seen by all members of each household over a 6-month period, it is likely that we are approaching the target that you have suggested of 90 percent of American homes receiving no fewer than 15 PSAs during any 6-month period.

The CHAIRMAN. Well, I think that this is enormously important, how many homes are really receiving these life saving messages and are we going to have to buy the ads to make it happen? If your testimony is that we are doing the job now with public services ads, there is not going to be much urgency to commit additional resources; but if you are not, and we are going to be serious about it, I think a strong case could be made for the purchasing of time.

If you are saying it is likely we are reaching the mark—I think you are going to have to provide us with the data or the measurements—how you draw that conclusion, because that is a very, very important point.

Dr. NOBLE. That is an important point.

The CHAIRMAN. So could you get back to us on that, provide that additional information for the record?

Dr. NOBLE. Yes, Senator.

Let me just say one thing on that question. The National Health Interview Survey questionnaire can be restructured, and we have talked about doing that, so that we can collect the aggregate data. At the moment, we are asking the questions: In the past month, what do you remember seeing? So we will have to collect that information in a prospective way.

We also will be working—we discussed this just yesterday—with the National Institute on Drug Abuse to add questions to their questionnaire, which will target specifically the IV drug-abusing community.

As you indicated, the difficulty is in reaching those at highest risk; even though the general population knowledge is good, the ads may not be reaching those at highest risk, and we need to put further effort into that.

The CHAIRMAN. I think you also have a question—I do not know how the question is posed, and maybe you could supply that to us—as to whether they just saw the ad, or whether they comprehended the message. As I understand professional evaluations, they consider both. I think the second aspect is important as well.

Dr. NOBLE. And although we are surveying the level of knowledge and misinformation, we all recognize that information alone is not sufficient to lead to behavior change. The real question that we all want an answer to is what are the behavior changes that are occurring–and even in an extension of that, ultimately, what we really need to know is the level of HIV infection in the population, which is determined best through seroprevalence studies.

The CHAIRMAN. Well, if you could provide whatever you have on that, it would be interesting, and very helpful.

Dr. NOBLE. Yes, we will provide that.

The CHAIRMAN. Thank you very much.

Dr. NOBLE. The Health Omnibus Programs Extension required that the Secretary, acting through the CDC, develop guidelines and curricula for firefighters, emergency medical technical technicians, and law enforcement officers, and provide those to the Department of Labor and to constituent groups.

The guidelines were completed and delivered by the Secretary's Office to the Department of Labor yesterday, and the guidelines and curricula will be delivered this week to State departments of health. We will be glad to provide those to you.

The CHAIRMAN. Could you make an estimate as to the number of police and firefighters that get training now around the country?

Dr. NOBLE. I would have to provide that for you.

The CHAIRMAN. But the point of these guidelines is obviously to increase it in a significant way.

Dr. NOBLE. Yes.

The CHAIRMAN. And you are satisfied that the States have been responsive and are working on this?

Dr. NOBLE. I think it is variable.

The CHAIRMAN. I do not know how we can review that. I do not know whether you do any studies or evaluation on it, but in the Congress, people are concerned about firefighters and other emergency response personnel, and it would be interesting for us to know what is happening around the country.

Do you have that kind of information?

Dr. NOBLE. As part of the development of these guidelines and curricula, we brought together consultants and created a special task force to help develop those curricula. The National Institute of Occupational Safety and Health has been responsible for that. I do not think that we have comprehensive and systematic data on that question, but we can certainly provide what we do have.

The CHAIRMAN. All right, fine.

While we are talking about what is happening in the States, what is your impression about the utilization of the States in terms of resources that you provide them in the area of education?

Dr. NOBLE. How effectively are they using it?

The CHAIRMAN. Yes. Do you do any type of evaluation on how they expend their AIDS resources? If you could tell us which are the best and what they are doing, I think that would be interesting for us.

Dr. NOBLE. As part of our cooperative agreements with every State and territory and local health department that receives Federal funds for AIDS prevention efforts, we require that they conduct evaluations, including surveys of knowledge, attitudes, and beliefs, so we have extensive information on that.

The problem of evaluating the effectiveness of educational efforts is a large one. We have been working with the Institute of Medicine of the National Academy of Sciences, whose report will be out tomorrow, to provide us with their best estimate of how to evaluate the behavioral interventions that we are funding and what kinds of additional evaluations are needed. We will be continuing to fund and work with the National Academy of Sciences in this current year to do exactly this kind of thing. Evaluation has become an increasingly important concern of ours. Since we have been working so hard and fast to get funds out, often using untested, unproven interventions, we feel that it is increasingly important to evaluate those.

The CHAIRMAN. Well, I think that will be very important, because they are resources that have been appropriated, and there have been some efforts in the Congress to interfere with sound scientific information and its distribution—I am not asking you to make any comment about it, but there have been attempts. I think it is important for us to be able to at least know whether the money that is being appropriated is getting out there and is effective in terms of communicating the best in terms of scientific information, or whether it is not.

I do not know whether you are going to do that or not.

Dr. NOBLE. We agree completely that appropriate targeted messages are required to get information out, and we will be working,

as we said, with evaluations at the State and local level, and under contract, to do some of this evaluation.

The CHAIRMAN. Well, you can tell of our interest in this, and we are going to continue to work very closely with you. We want to support those efforts of the Centers that encourage and provide the best of scientific information to the various groups at risk; and we are looking at how it can be most effective. So we will be looking forward to that.

Please continue.

Dr. NOBLE. I have only one closing comment. With regard to management enhancements and physical plant expansion, I am pleased to report that because of the support of the Administration and the Congress, significant progress has been made. The administration requested, and Congress funded, the construction of one office building and the lease purchase of one laboratory and two additional office buildings. As we speak, my office is being moved into leased office space today.

The CHAIRMAN. You hope.

Dr. NOBLE. And we are looking forward to the completion of the buildings I just mentioned, so that in due course we can move back into a consolidated location.

The FTE estimate for AIDS for fiscal year 1989, as it appears in the fiscal year 1990 budget, is 523, an increase of 34 over what we reported for fiscal year 1988. In the fiscal year 1990 budget sent to Congress, 635 FTE's are requested, an increase of 112, or 21 percent.

Mr. Chairman, that concludes my testimony. I will be glad to answer any questions from you or other members.

[The prepared statement of Dr. Noble follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

STATEMENT OF

GARY R. NOBLE, M.D.
ASSISTANT SURGEON GENERAL

DEPUTY DIRECTOR (HIV)

CENTERS FOR DISEASE CONTROL

PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

FEBRUARY 7, 1989

Mr. Chairman and Members of the Committee:

I am Dr. Gary Noble, Deputy Director (HIV), Centers for Disease Control (CDC), and Director of the HIV/AIDS programs of the CDC. I am pleased to represent the CDC in discussing our comprehensive information/education efforts to assist states, localities, and private groups to prevent HIV infection.

HIV infection remains a major public health problem in the United States. As of January 23, 1989, a total of 84,503 cumulative cases of AIDS has been reported to CDC since AIDS was first recognized nearly eight years ago. Over half of these reported cases are known to have died. As of January 2, 1989, 32,311 cases were reported for 1988, an increase of 10,956 cases, or 57 percent, over the 21,355 cases reported for the same period in 1987. Of the 1,375 children reported with AIDS since 1981, 583 cases were recorded during the past year, which represents a 77 percent increase over the 332 cases reported in 1987. Minority populations continue to be disproportionately affected by AIDS. Blacks account for 26 percent of the total cumulative adult cases and 52 percent of the pediatric cases. Hispanics account for 15 percent of the reported cumulative adult cases and 23 percent of the pediatric cases. Although these two groups comprise only 20 percent of the nation's population, they account for 41 percent of the adult cases and 75 percent of the pediatric cases.

The strategy to control the spread of HIV infection is influenced by five crucial facts: (1) no effective therapies exist to eliminate the virus or prevent its growth in the infected patient; (2) no vaccine exists to prevent susceptible persons from acquiring infection; (3) infected individuals may transmit the virus continually, or intermittently, throughout their lifetimes; (4) spread of the virus results from a few personal behaviors which, when altered, can prevent or reduce the possibility of transmission to a minimum; and (5) HIV infection represents the first modern infectious disease causing significant morbidity and mortality for which health promotion is the major intervention tool.

CDC's mission is to prevent HIV infection and reduce unnecessary morbidity and mortality associated with it. Health promotion is the major intervention tool. CDC attempts to reduce HIV transmission by influencing the behavior of people in three specific categories: persons who are already infected, so they will adopt behaviors that reduce their risk of spreading the virus to others; individuals who are uninfected, but whose current personal behaviors place them at high risk of acquiring an infection; and the general public, who must have timely and accurate information that prevents unjustified fears, facilitates rational behavior toward all aspects of the HIV epidemic, and promotes constructive support for the control efforts of public health officials.

CDC's major HIV prevention efforts directed toward persons at increased risk are conducted through cooperative agreements with 50 state, 7 territorial and 5 local health departments. Counseling, testing, and partner notification services, as well as health education /risk reduction activities, are critical components of the HIV prevention program.

The only method available to us to contain the epidemic is to convince people to avoid personal behaviors that could put them in contact with the virus. Testing, in the absence of counseling, merely informs individuals whether or not they have been infected with the virus. Counseling, along with testing, offers an opportunity to educate a person about the high-risk behaviors that can cause the individual to become infected with HIV or pass the infection to someone else. A major portion of CDC's HIV budget for FY 1989 ($100 million, or 26 percent) supports counseling, testing and partner notification programs. The early diagnosis of HIV infection takes on increased urgency in light of recent information that aerosolized pentamidine given to asymptomatic HIV infected individuals with low CD4 cell counts can reduce the risk of pneumocystis pneumonia.

A number of studies conducted in both the United States and other countries have examined the effect that knowledge of test results has on the behaviors of people who have been tested for HIV antibody. Most of these studies, which involve homosexual men, indicate that the greatest effect on behavior seems to result from having the test done. Much needs to be done in this area, but preliminary studies indicate that persons with positive tests are more likely to change their risky sexual behavior than persons with negative tests.

In FY 1989 it is estimated that approximately 1.5 million counseling sessions will be conducted through State and local health departments and nearly 900,000 tests will be performed with Federal support. Partner notification is a key element of the HIV prevention process. All health departments receiving Federal funds are required to have a partner notification plan in place.

Health education/risk reduction activities are designed to provide specifically targeted messages to well-defined high-risk populations. For example, face-to-face risk reduction messages are delivered to IV drug abusers in selected communities by outreach workers.

To assess the current status of knowledge, attitudes, and beliefs (KABs), States and local health departments are required to conduct surveys in their respective jurisdictions. Subsequent surveys of KABs may then be utilized to assess the effect of our prevention efforts.

Since health education techniques dominate the current strategy for controlling transmission of HIV, it is essential that the most effective methods of applying these techniques be tested under actual program conditions and disseminated to all States. Towards these ends, CDC has been funding six cooperative agreements since 1985 to support on-going community-based demonstration projects for HIV prevention and risk reduction. The findings of these projects will continue to be evaluated and disseminated to the other prevention projects areas.

Perinatal AIDS Prevention Projects have been funded to encourage the effective use of contraception among HIV-infected women and women at high risk of infection who wish to avoid pregnancy. A total of $6.3 million was available to fund eight such projects in both fiscal years 1988 and 1989, and $11.5 million is requested to continue support in fiscal year 1990. These projects will: 1) determine and seek to overcome obstacles which discourage effective use of contraception among target populations; 2) facilitate the use of family

planning services among target populations; 3) evaluate attitudinal factors related to use of contraception among HIV-infected and high-risk women; and 4) encourage behavioral change among HIV-infected and high-risk women to reduce risk of transmission or acquisition of HIV.

Minority HIV Programs

Because HIV infection has disproportionately affected minority populations, CDC recognizes the critical need for increased efforts to reach minority populations. In August 1988, an Assistant Director for Minority Health was appointed at CDC, and in November 1988 the position of Special Assistant for Minority (HIV) Policy Coordination was created in the Office of the Deputy Director (HIV). A nationwide search is currently in progress to fill the position on a permanent basis by May 1989.

Since FY 1987, CDC has provided funds for organizations that serve and/or represent minority populations, through the minority initiative component of the HIV/AIDS Prevention Cooperative Agreements with State and local health departments. During FY 1987, $4.3 million was awarded to 124 such organizations; in FY 1988, $13.1 million was awarded to over 300 organizations; and in FY 1989, approximately $15 million has been awarded to States in the minority initiative component. It is expected that the number of minority community-based organizations approved for funding through State and local governments will again exceed 300 in this fiscal year.

During FY 1989, Congress authorized that $10.5 million be awarded directly to approximately 75 community-based organizations. Of this amount, at least $5 million will be awarded to organizations that serve and represent minority populations in 27 metropolitan area having the largest number of reported AIDS cases. Awards will range between $20,000 and $225,000, and will average approximately $130,000.

Funds are also being provided to the United States Conference of Mayors to support HIV information exchange and to expand funding to minority-oriented, community-based organizations (37 in 1988) interested in conducting HIV information programs.

In August 1988, CDC awarded more than $6 million to 33 national and regional organizations that serve minority populations, primarily black and Hispanic, to assist in developing special approaches to these populations and to expand public information efforts directed towards minorities. Though only in place for a short time, these grants have produced a number of training programs and information materials that are addressing the needs of geographically, culturally, racially, and ethnically diverse people. The project director for one of these grantees, Yolanda Serrano, was recently named Woman of the Year by Ms. Magazine, for her prevention and outreach efforts among drug users and prostitutes in New York City. Our grant to this organization "Association for Drug Abuse Prevention and Treatment, Inc." (ADAPT) will provide training programs to other localities for conducting similar outreach programs.

Approximately $1.0 million will be awarded through cooperative agreements to national AIDS organizations, national health organizations, national non-health organizations, and trade and business organizations. These cooperative agreements will lead to the development of effective AIDS information and education programs among constituents of these organizations.

School Health HIV Education

In the area of school health education, CDC awarded cooperative agreements in FY 1987 to 15 national organizations to assist schools and other agencies serving youth in providing effective education about HIV. Of the 15 national organizations funded, five specifically targeted their efforts toward black and Hispanic youth. In FY 1988, five additional organizations were funded, for a total of twenty.

Approximately one out of every five Americans diagnosed with AIDS is between the ages of 20 and 29. Given an average incubation period of about seven years between infection with-HIV and diagnosis of AIDS, some portion of those in the 20-29 year-old age group diagnosed with AIDS were infected as teenagers. More than 45 million students are enrolled in grades kindergarten through twelve, and an additional 12 million students are enrolled in colleges and universities. Thus, of the total population of 247 million persons in the United States, about 25 percent are in schools and colleges. In fiscal year 1988, $29.9 million was devoted to preventing HIV infection in school and college aged youth. In fiscal year 1989 $35.7 million was appropriated and

$42.6 million is requested for fiscal year 1990. CDC's program to reach this age group is composed of six integrated operating systems to enable schools, and other agencies that serve youth, to implement programs that can help young people avoid HIV infection and other important health problems:

1. The twenty national organizations work as a coalition to help schools and other agencies that serve youth nationwide to implement effective programs to help young people avoid risks for HIV infection and other important health problems. These organizations receive fiscal and technical assistance from CDC through cooperative agreements, and include, for example, the National School Boards Association, Council of Chief State School Officers, National Network of Runaway & Youth Services, American Association of School Administrators, National PTA, American College Health Association, and 14 others.

2. In FY 1988, every State, five Territorial, and 16 local departments of education received fiscal and technical assistance from CDC through cooperative agreements. These departments work with the national organizations described above and with their respective health departments to assist schools and other agencies that serve youth nationwide in implementing effective programs to help young people avoid risks for HIV infection and other important health problems.

3. A materials development and information dissemination system has been established to identify, develop, and provide information about interventions that can be used to help school- and college-aged

populations avoid risks for HIV infection and other important health problems. These materials include curricula, films, videotapes, audiotapes, policies on health education, policies on disease and injury control, books, teacher training programs, materials for parents, brochures, etc.

4. Training and demonstration centers have been established to train school and community personnel to implement state-of-the-art interventions that can help young people avoid risks for HIV infection and other important health problems. A total of $1.4 million was budgeted for this activity in FY 1988. The FY 1989 and 1990 estimates are $3.5 million and $3.6 million respectively. Two national centers provide training for State-based teams, and one national center provides training for city-based teams from across the Nation. Twelve smaller regional training centers train school and community personnel in their regions to implement comprehensive school health education curricula.

5. A survey research system has been established to monitor the prevalence of HIV-related knowledge, beliefs, and risk behaviors among national probability samples of high school students over time; to monitor State school HIV infection control and education policies; to help State and local departments of education monitor the percentage of students who receive HIV education and comprehensive school health education; and, to help State and local departments of education monitor the prevalence of HIV-related knowledge, beliefs, and risk behaviors among high school students over time.

6. An evaluation research system was established in FY 1988 to conduct experimental research about the effectiveness of specific disease interventions, and to identify principal determinants of behaviors that may lead to HIV infection or other health risks, and to help State departments of education evaluate and consequently improve their efforts to reduce risks for HIV infection and other health problems.

In the area of general information for the public, CDC launched the first phase of the National Information Campaign, "America Responds to AIDS", in October 1987 with the distribution of 38 public service announcements (PSA's) to television, radio, and print media nationwide. Three phases of the campaign have now entered media channels: The General Information phase (October 1987); The National Mailer "Understanding AIDS" phase (May/June 1988); and The "Women at Risk" and "Sexually Active Adults With Multiple Partners" phase (October 1988). The fourth phase "Parents and Youth" will be released in April 1989.

Broadcast Advertisers Report (BAR) data, generated by trained editors who review magnetic tape recordings of broadcast activity by national and selected local network, cable, and radio stations, indicate that the "America Responds to AIDS" campaign soon became the dominant public service campaign in the Nation. The campaign has received more than $23 million of free airtime during its first 14 months of activity ending November 30, 1988.

Print materials have been distributed in a variety of ways. A catalog of materials designed for transit vehicles use was distributed to the 400 companies using materials of this type.

It is difficult to isolate the coverage in the press related specifically to the Federal Government's "America Responds to AIDS" national information campaign from the total coverage in AIDS. For the National Mailer "Understanding AIDS", however, we were able to monitor newspaper coverage linked directly to an item or event. During May and June 1988, a total of 1,376 articles for the general public were identified, representing 350 million potential reader impressions; 86 articles were identified for the black audience, representing 16.7 million reader impressions, and 86 articles were identified for the Hispanic audience, representing 9.8 million reader impressions.

The major channels for requesting and distributing printed information are the National AIDS Hotline and the National AIDS Information Clearinghouse. Although the National AIDS Information Clearinghouse and the National AIDS Hotline are managed by separate contractors, they are electronically linked

with each other. Requests to the Hotline for printed materials are fulfilled through the Clearinghouse. Databases of HIV services are available to Hotline information specialists for rapid computer searches, so that callers may obtain direct referral service. During fiscal year 1988, the Hotline, which also serves the hearing impaired, handled over 2 million calls, a volume of calls five times larger than any healthline service had ever received

previously. The Clearinghouse, in turn, distributed an average of more than 1 million publications on HIV infection per week during its first year of operation. Again, this is a volume of need fulfillment unprecedented in public health history.

We concur in the need for a professional hotline service as outlined in P.L. 100-607. We believe this could be accomplished as part of the Clearinghouse system, coordinated by the Public Health Service. Specific information would be included, e.g., data on clinical trials, drug protocols and licensure, and emergency response data. Various options are currently being explored for implementing this professional hotline.

The national household brochure mailing was accomplished in May and June of 1988. Distribution of 112 million copies of "Understanding AIDS" in English, Spanish, and in Braille, was completed by June 15. In addition to the household mailing, copies were also provided to the military, correctional institutions, shelters for the homeless, and to Federal employees assigned to posts overseas. Copies continue to be requested from the Clearinghouse. Translations in Chinese and Portuguese are currently being distributed.

Indicators of our effectiveness in informing the general public are provided by our National Center for Health Statistics (NCHS) through the National Health Interview Survey. Beginning in September 1987, NCHS has included an AIDS knowledge and attitudes survey in its continuous, cross-sectional household survey of the adult, civilian population. From this survey, we know that knowledge levels about the actual transmission routes for HIV are

extremely high. For example, 95 percent of American adults believe that the virus is very likely to be transmitted through sharing needles for drug use with an infected person. The data also show that, although numerous misperceptions persist, success in altering erroneous notions is occurring.

The most recent data we have from the National Health Interview Survey for the months of May through August 1988, indicate that an average of 85 percent of the adults surveyed could recall seeing a PSA about AIDS on television in each of the 4 months surveyed (Enclosure 2). Although the survey questionnaire did not ask for aggregate data for the total number of PSAs seen by all members of each household over a 6 month period, it is likely that we are approaching the target of 90 percent of American homes receiving no fewer than 15 PSAs during any period of six months.

With regard to management enhancements and physical plant expansion, I am pleased to report that because of the support of the Administration and the Congress, significant progress has been made.

We are now in the process of occupying CDC's newest facility, the Virology and Rickettsia Laboratory which will house most of CDC's HIV/AIDS laboratory research and service activities. In addition, the Administration has requested and Congress has funded one office building and directed the lease purchase of one laboratory and two additional office buildings.

96-391 O - 89 - 7

The FTE estimate for HIV/AIDS for fiscal year 1989, as it appears in the FY 1990 budget, is 533, which is an increase of 34 over what we reported for fiscal year 1988. In the fiscal year 1990 budget sent to Congress, 635 FTEs are requested, which is an increase of 112 or 21 percent.

Mr. Chairman, that concludes my testimony. I shall be glad to answer any questions which you or any other members of the committee may have.

The CHAIRMAN. Again, this is not your doing, but as I understand, that comes out to 146 new FTE's as opposed to 350 authorized in S. 1220. I would just make that point for the record.

Dr. NOBLE. If I might comment on that.

The CHAIRMAN. Yes.

Dr. NOBLE. The Health Omnibus Programs Extension Act requested an annual report, I believe, on the FTE situation, and in looking at the draft of that, the FTE's on-board as of December last year, if annualized, would be 555. We have been told not to allow an FTE ceiling to impede our hiring to complete our AIDS programs, and so we will plan to continue to hire required FTEs.

The CHAIRMAN. Well, as I understand, that is moving one group out of some very important functions into another area of important functions, rather than adding onto the whole effort in terms of AIDS. I do not know whether you wish to comment on that or not.

Dr. NOBLE. Since I am not responsible, fortunately, for all of CDC's programs, I cannot comment directly on that, but we would be happy to provide information to you for the record.

In discussing this with the Director of CDC yesterday, I was assured that there was no intention to divert FTE's from other essential programs, however.

The CHAIRMAN. All right. We appreciate your response on that.

Senator Dodd?

Senator DODD. Just one question, if I can, Dr. Noble. I applaud your efforts, and obviously the public service announcements. Any educational effort really is paramount—drug abuse prevention, human sexuality and the like.

The AIDS amendments bill provided for some educational assistance in the school systems. I wonder if you could just briefly describe to what extent CDC has developed curricula for schoolchildren and whether or not in fact they are reaching younger children, to what extent they are reaching younger children, and to what extent you are getting State cooperation in both the drug prevention efforts and human sexuality as part of school curricula.

Dr. NOBLE. As I stated in my testimony, with one out of four of the U.S. population in school and college, it is a tremendously important population. We released a recommendation for material content for every grade of school over a year ago. It took a year to bring something to that stage, to get the agreement of all of the parties, but we felt it was a very important contribution. It was not model curricula, however, since it is our feeling that the specific final message should be developed at the local level.

There has been variable progress in getting State and local boards of education to implement required education for prevention of HIV infection.

I will have to provide for the record the number of States that do require AIDS education. I know that some time ago it was only 17; I know that now more than that that do require some education. We would like to see all States requiring age-appropriate AIDS education.

With regard to a question you asked Dr. Matheny about the IV drug abuse problem and children, our data indicate that 73 percent of infants born to infected mothers are born to mothers who were themselves IV drug abusers or were the sexual partners of IV drug

abusers. So clearly, the IV drug abuse problem is the major reason for pediatric HIV infection.

Senator DODD. And we can expect that number to grow.

Dr. NOBLE. Yes. Clearly, the fastest-growing segment of the AIDS problem results from the IV drug abuse problem.

Senator DODD. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much. We will submit additional material for the record, including statements from the other Members of the committee.

[The prepared statements of Senators Pell and Cohen, and additional material supplied for the record follow:]

STATEMENT OF SENATOR CLAIBORNE PELL

FEBRUARY 7, 1989

LABOR AND HUMAN RESOURCES COMMITTEE

"AIDS EDUCATION, CARE, DRUG DEVELOPMENT AND OVERSIGHT I"

Mr. Chairman, I thank you for holding this important hearing so early in the 101st Congress. As you well know, members of this Committee worked very hard last year to produce a bill, both in Committee and in the Senate, that would do more than just touch upon the AIDS crisis. We wanted to combat that crisis, promptly and effectively, and we wanted to give to public health officials, health care providers, and community service organizations the tools that would make a real difference in the fight against AIDS.

Time was of the essence then, as it is now. And it is as important that we monitor closely the fruits of our labors as it is that we undertook this effort at all.

Mr. Chairman, some of what we may hear today may not adequately assure the American people, or the members of this Committee, that the federal government views AIDS as the devastating public health crisis that it is. It is my hope, and my intent, to ensure that the sense of urgency felt by the medical community, AIDS victims and their families, and the general public is transformed fully and effectively into prompt government action. We owe at least that comfort to the dying, and the hope of life and good health to the living.

I look forward, Mr. Chairman, to hearing from today's witnesses, and wish to thank them in advance for what I am sure will be informative and useful testimony.

Statement by Senator Thad Cochran

Hearing Record
Senate Labor and Human Resources Committee
February 7, 1989

Mr. Chairman,

Thank you for giving the committee the opportunity to hear from these distinguished witnesses regarding the current status of AIDS education, care and drug development. Certainly, we appreciate the leadership they are providing to our federal and private agencies engaged in the enormous challenge of combatting the AIDS virus.

There is one issue, in particular, that I want to emphasize today. With the additional demands placed on the Food and Drug Administration due to the AIDS crisis, I am especially concerned about the critical need for revitalizing this important agency.

The FDA, simply put, is responsible for protecting the health of the Nation against impure and unsafe food, drugs

and cosmetics and other potential hazards. And it takes substantial resources to effectively accomplish this ongoing mission. Unfortunately, through the years, the resources of the FDA have fallen far short of the growing demands placed upon it. It is with some alarm that I learn more about the current strains under which this vital agency is operating.

There are several key matters which must be addressed. The agency must be able to attract the best scientists in the country and to do so we must pay competitive salaries. The agency must have adequate facilities to conduct its important work, and it is essential that it have state-of-the-art equipment. In addition, fundamental changes are needed in the basic mandate of the Food and Drug Administration, authorized in 1938, to better reflect today's realities of new technologies and developments affecting procedures and statutory standards.

I lend my full support to this revitalization effort and am willing to work on this matter both through the authorizing and appropriating committees in the Senate.

United States General Accounting Office

GAO

Report to the Honorable
Barbara Boxer, House of Representatives

December 1988

AIDS EDUCATION

Activities Aimed at the General Public Implemented Slowly

GAO/HRD-89-21

GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-230539

December 16, 1988

The Honorable Barbara Boxer
House of Representatives

Dear Ms. Boxer:

In response to your request of December 10, 1987, and subsequent discussions with your staff, we have reviewed selected aspects of the administration's Acquired Immunodeficiency Syndrome (AIDS) education programs. Overall, you were concerned with what you considered to be inexcusable delays in implementing a thorough, effective national AIDS education program. You asked us to look at six aspects of the Centers for Disease Control's (CDC's) AIDS education program for the general public, including its budgetary resources, and specific educational interventions, such as the nationwide mailing, public service announcements, and the national AIDS hotline.

Background

CDC, under the Department of Health and Human Services (HHS), is the principal federal agency responsible for preventing AIDS through education. CDC's AIDS activities include education programs aimed at curtailing the spread of the epidemic and epidemiology and surveillance programs. Through these activities, CDC tracks the spread of AIDS and can better target AIDS education efforts. Between fiscal years 1984 and 1988, CDC's total AIDS budget grew more than 100 percent each year on average, from about $14 million to over $300 million.

Several organizations within CDC share responsibility for AIDS education. Two—the Center for Health Promotion and Education and the Center for Prevention Services—have responsibility for targeting specific groups, including school and college-aged youth, health care workers, and persons at increased risk of infection. In addition, the Office of Deputy Director for AIDS coordinates CDC's overall AIDS program and administers CDC's education efforts aimed at the general public.

To focus national attention on AIDS and increase the general public's knowledge of the disease, CDC planned a fall 1987 national AIDS information campaign. To begin the campaign, the President designated October as national "AIDS Awareness and Prevention Month." CDC planned key activities to begin in October to provide factual information about the disease and how to prevent its spread, as well as to positively influence attitudes about AIDS.

In addition to mailing AIDS information to every American household, CDC planned to (1) distribute television, radio, and print media public service announcements, (2) expand CDC's national AIDS telephone hotline to respond to inquiries resulting from the national information campaign, (3) create a national AIDS information clearinghouse distribution system, and (4) conduct public meetings and forums across the nation to discuss AIDS prevention.

Methodology

As agreed with your office, our review focused primarily on the budgetary and operational aspects of the National AIDS Information and Education Program activities. You specifically asked us to examine the (1) CDC AIDS education budget and expenditures, (2) delays in the nationwide mailing of AIDS information to all households and disposition of funds intended for this activity, (3) airings of televised AIDS public service announcements, (4) operation of the national AIDS telephone hotline, (5) distribution of the pamphlet, What You Should Know About AIDS, and (6) status of other projects intended to educate the public at large about AIDS.

We interviewed officials of HHS and the U.S. Government Printing Office (GPO) and representatives of three government contractors working with CDC on AIDS television public service announcements, the telephone hotline, and the information clearinghouse. In addition, we interviewed network television officials regarding public service announcements and an American Telephone and Telegraph Company official concerning the hotline. We also requested an interview with the Assistant to the President for Policy Development to discuss the nationwide mailing of AIDS information. He declined our request. Finally, we collected and reviewed documentation at CDC and the hotline contractor's office.

Our work was performed between January and August 1988 in accordance with generally accepted government auditing standards. At your request, we did not obtain agency comments, but we did discuss our work with CDC officials and their comments have been incorporated where appropriate.

Results in Brief

Although CDC's budget for AIDS education increased significantly between fiscal years 1985 and 1988, its efforts to focus national attention on AIDS prevention were impaired by the slow implementation of key activities aimed at the general public. CDC in May 1987 selected October as "AIDS Awareness and Prevention Month," but it could not get

clearance from the White House Domestic Policy Counsel for its national mailing of AIDS information—the centerpiece of the campaign. Also, CDC officials acknowledge that their schedule allowed limited time to conduct their planned activities. For example, contracts for major education activities were not awarded until July 31, 1987, or later.

Principal Findings

Education Budget Increased Significantly

HHS's budget for AIDS education activities has grown significantly, from $17.5 million in fiscal year 1985 to about $300 million in fiscal year 1988. Most goes to CDC; over the same period, CDC's AIDS education budget has grown from about $17 million to nearly $210 million.

About 40 percent of CDC's total 1988 budget is allocated to AIDS activities, and 69 percent of these funds is for AIDS education. Our review showed that CDC obligated AIDS education funds for AIDS education activities through 1987 and that none was reprogrammed for other purposes.

Mass Mailing Delayed

In July 1987, CDC abandoned plans for the October 1987 nationwide household mailing of AIDS information because it could not obtain clearance from the White House Domestic Policy Counsel. The decision not to go forward was made despite the explicit but nonbinding desire of the congressional conference committee for a mass mailing. CDC obligated the funds the committee intended for the mailing—about $20 million—for other AIDS education activities. The following year, the Congress mandated in law that CDC conduct the mailing by June 30, 1988, and again appropriated funds for it. In compliance with this law, CDC completed mailing of the brochure, Understanding AIDS, in June 1988.

Airings of Televised Public Service Announcements Limited

Although 38 CDC-produced AIDS public service announcements were distributed to the major networks on September 30, 1987, television monitoring data show only one airing by a major network in October 1987. The three major networks aired CDC public service announcements on a total of six occasions in November 1987. Copies of the announcements were provided to local stations in mid-October. Between December 1987 and February 1988, nearly 90 percent of all network-aired AIDS public service announcements were shown during nonprime-time viewing hours, with 59 percent being shown between 11 p.m. and 7 a.m.

Access to Telephone Hotline Uneven

In October 1987, CDC expanded its AIDS telephone hotline from 17 to 68 lines to handle increased calls expected from AIDS Awareness and Prevention Month activities. Nevertheless, telephone hotline access was still difficult at times. CDC's contract set an acceptable monthly busy-signal rate of 3 percent. Between October and December 1987, however, monthly average busy-signal rates on operator-assisted lines ranged from 38 to 65 percent. By the summer of 1988, however, the hotline contractor reported a 7-percent busy-signal rate. Unacceptably high busy-signal rates continued to occur immediately after televised public service announcements were aired, however, and CDC and its contractor are working to resolve this situation.

More Timely Distribution of AIDS Pamphlet

Also, in September 1987, CDC set up a national AIDS Information Clearinghouse under contract. As of July 1988, CDC had distributed nearly 24 million copies of the pamphlet, What You Should Know About AIDS, through its contractor and the GPO. In January, February, and March, we placed orders for the pamphlet to determine whether they were being distributed within 6 workdays, as required by contract. While our earlier orders took an average of 12 workdays, March deliveries were received in a timely manner.

Status of Additional AIDS Education Activities

Beginning in October 1987, CDC sponsored additional activities and events aimed at the general public. Available data indicate that many of these projects varied in scope and timing. The projects included distributing radio and print media public service announcements, holding public meetings and leadership forums in cities across the nation, sending information sheets to three targeted cities, conducting a technical briefing in conjunction with the American Medical Association, and making agency officials available for speaking engagements.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Secretary of HHS, the Director of CDC, and other interested parties and make copies available to others on request.

The major contributors to this report are listed in appendix VII.

Sincerely yours,

Janet L. Shikles

Janet L. Shikles
Associate Director

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Abbreviations

ABC	American Broadcasting Company
AIDS	acquired immunodeficiency syndrome
CBS	Columbia Broadcasting System
CDC	Centers for Disease Control
GPO	U.S. Government Printing Office
HHS	Department of Health and Human Services
NBC	National Broadcasting Company

Appendix I

CDC's AIDS Education Budget and Planned Expenditures (Fiscal Years 1985-1988)

For fiscal years 1985 through 1988, HHS allocated $489.6 million to AIDS education activities. Included in the overall HHS total were $365.3 million in CDC's expenditure plan for AIDS education activities and over $100 million for activities led by the Alcohol, Drug Abuse, and Mental Health Administration to educate intravenous drug users and the Health Resources and Services Administration to educate health care workers. The annual funding amounts are shown in table I.1.

Table I.1: CDC and HHS AIDS Education Funds (Fiscal Years 1985-1988)

Dollars in millions

Fiscal year	CDC	Other HHS	Total
1985	$16.7	$0.8	$17.5
1986	34.2	5.3	39.5
1987	104.7	27.8	132.5
1988	209.7	90.4	300.1
4-year totals	**$365.3**	**$124.3**	**$489.6**

CDC's AIDS budget for education and other activities is shown in table I.2.

Table I.2: CDC AIDS Budget (Fiscal Years 1984-1988)

Dollars in millions

Fiscal year	Education	Epidemiology and surveillance	Total	Increase (percent)
1984	$0.9	$12.9	$13.8	-
1985	16.7	16.6	33.3	141
1986	34.2	27.9	62.1	86
1987	104.7	31.3	136.0	119
1988	209.7	95.2	304.9	124

CDC apportioned its AIDS education program funds among four target groups and various program activities within each target group, as shown in table I.3.

Table I.3: CDC AIDS Education Expenditure Plan by Target Group/ Activity (Fiscal Years 1985-1987)

Dollars in thousands

	Fiscal year			
Target group/activity	**1985**	**1986**	**1987**	**3-year total**
Persons at increased risk:				
Health education/risk reduction	$1,049	$11,239	$14,600	$26,888
Counseling/testing	10,995	10,981	33,200	55,176
Minority initiatives	•	•	7,000	7,000
Demonstration projects	1,180	3,732	4,200	9,112
Innovative risk reduction	•	1,615	500	2,115
Conference of Mayors	320	250	300	870
Hemophilia project	•	2,500	3,500	6,000
Perinatal AIDS prevention	•	•	1,900	1,900
General public:				
Hotline	•	2,245	2,300	4,545
Clearinghouse	•	•	3,000	3,000
National information activities	2,941	1,500	21,500	25,941
Health care workers—laboratory training and evaluation	65	65	1,400	1,530
School/college-aged youth:				
National efforts	•	•	2,300	2,300
Material development and dissemination	136	114	1,300	1,550
State/local projects	•	•	7,700	7,700
CDC AIDS education totals	**$16,686**	**$34,241**	**$104,700**	**$155,627**

We reviewed AIDS financial reports for each of the above fiscal years. According to these reports, essentially all funds CDC allotted for the AIDS education program were obligated for AIDS education activities. Further, our review of major program obligations showed that CDC obligated the funds for the target group/major activities essentially as planned.

Between 1985 and 1987, CDC provided $97 million to state and local health and education departments in the form of cooperative agreements. Eighty million of this went to health departments for health education/risk reduction and counseling and testing activities. For these funds, we reviewed but did not independently verify the expenditures the states reported. As of September 1987, the states reported spending virtually all of the counseling and testing funds awarded in fiscal year 1985. As of March 1988, most of the states reported spending about 85 percent of the 1986 funds and about 25 percent of the 1987 funds.

National information activities, including the operation of an AIDS hotline, an AIDS clearinghouse, and national media campaigns, were funded primarily through contracts rather than state and local governments. Upon review of these contracts, we determined that CDC obligated these funds for AIDS national information activities.

Appendix II

Plans and Funding for the Nationwide AIDS Information Mailing

In January 1987, CDC developed the idea of mailing AIDS information to all households in the country as the centerpiece of its National AIDS Information and Education Program. CDC proposed that the mass mailing coincide with other activities planned for the October 1987 national AIDS campaign.

From February 1987, CDC worked toward building a consensus of support for the project within HHS and developing and pretesting an information brochure for the mass mailing. Pivotal issues included the sensitive nature of the content of the brochure, whether a single brochure could be produced that would be useful to all households throughout the country, whether funds would be more effectively used if targeted toward high-risk groups rather than the general population, and the overall cost-effectiveness of the effort.

These issues were resolved in favor of the mailing, and official requests for approval and funding were made in May 1987. In July 1987, the Congress appropriated $20 million in supplemental funds to CDC for "disease control, research, and training." The House and Senate conferees, in their report on the appropriations bill, indicated that CDC should use the funds for a nationwide mailing. None of the funds, however, were designated in the legislation as reserved for such a mailing; consequently CDC was not legally required to spend any of this amount to finance the mailing.

A May 4 meeting of the White House Domestic Policy Council and the President signaled the turning point in the decision-making process. CDC and HHS officials stated that the Council decided to defer approval of a nationwide mailing until review of the proposal by the Presidential Commission, which did not meet until September 1987. This effectively stopped the mailing as part of the October 1987 campaign, because the necessary clearances would not be ready.

In December 1987, the Congress directed CDC to complete the nationwide mailing by June 30, 1988, using funds appropriated to CDC for fiscal year 1988 for disease control. CDC complied and completed mailing the brochure, Understanding AIDS, to households by June 1988—8 months after AIDS Awareness and Prevention Month.

Once CDC acknowledged in July 1987 that the mass mailing could not be accomplished as part of the October 1987 campaign, CDC managers began to plan for other appropriate uses of the supplemental funds. Most of the $20 million was obligated to expand advertising, hotline, and

clearinghouse activities by funding multiyear contract options already negotiated and to print additional quantities of various AIDS publications, as table II.1 shows.

Table II.1: CDC's Obligations for the $20 Million Appropriated for the 1987 AIDS Mailing

Dollars in thousands

Use of funds	Amount
Advertising agency contract	$6,850
Hotline contract	6,232
Clearinghouse contract	2,323
Printing	2,812
Cooperative agreements	1,171
Other	900
Total	**$20,288**

Appendix III

Airings of Televised Public Service Announcements

On July 31, 1987, CDC contracted with Ogilvy and Mather, a national advertising agency, to develop AIDS television public service announcements, also called spots, of varying length and content. On September 30, 1987, 38 spots were provided to the American Broadcasting Company (ABC), Columbia Broadcasting System (CBS), and National Broadcasting Company (NBC). In addition, in mid-October copies were distributed to 1,584 individual television stations.

Although CDC had expected the television public service announcements to be shown in October, during that month only ABC broadcast a CDC spot and it was aired only once, on October 28. NBC and CBS asked for and were furnished revised editions of the spots, which they began airing on November 16 and November 30, respectively. In total, the three major networks showed AIDS spots six times during November 1987.

Between December 1987 and February 1988, the three major networks aired CDC spots on 228 occasions. The estimated value of this air time was $3.9 million. We do not know how many of these network spots were aired by the local affiliated stations, which could pre-empt them. Also, during the same period, local stations aired CDC public service announcements on 1,213 occasions. This air time was valued at an estimated $482,000.

In addition to the CDC-produced spots, the networks and local stations had available for airing AIDS public service announcements produced by other organizations, such as the American Red Cross and the American Foundation for AIDS Research. On average, about one-third of the total AIDS spots aired by the stations and networks were those produced by CDC. Table III.1 summarizes and compares CDC to total AIDS public service announcement airings.

Table III.1: Number of CDC Spots and Estimated Value of Air Time (December 1987-February 1988)

Network/station	CDC spots		Estimated value of air time for CDC spots	
	Number	Percent of total spots	Dollars	Percent of total spots
Major networks:				
ABC	66	43	$1,192,964	39
CBS	134	29	796,150	22
NBC	28	57	1,901,799	63
Subtotals	**228**	**35**	**$3,890,913**	**41**
Local markets:				
Atlanta	112	55	$44,370	54
Boston	19	3	14,193	4
Chicago	131	46	40,067	47
Cleveland	113	66	18,799	63
Dallas	217	69	42,204	40
Detroit	12	3	4,003	3
Houston	52	57	22,707	69
Los Angeles	0	0	0	0
Miami	5	10	905	6
Minneapolis	122	60	25,190	60
New York	72	18	39,853	17
Philadelphia	167	53	162,187	73
Pittsburgh	102	84	35,692	85
San Francisco	20	7	11,888	7
Seattle	59	40	19,072	61
Washington, D.C.	10	9	945	3
Subtotals	**1,213**	**30**	**$482,075**	**27**
Totals	**1,441**	**30**	**$4,372,988**	**38**

In some local markets, stations showed mostly CDC spots; in other markets, including those with some of the highest AIDS caseloads, stations concentrated on the non-CDC-produced spots. For example, Los Angeles stations aired no CDC-produced spots but did show 294 other AIDS spots, as the table indicates.

More importantly, nearly 90 percent of the network-aired AIDS spots—both the CDC and non-CDC spots—were aired during nonprime time, CDC records show (see table III.2). Moreover, 59 percent of network spots were aired after 11 in the evening.

Table III.2: Time of Day AIDS Spots Aired
(December 1987-February 1988)

Source	7:00 am to 5:00 pm	5:00 pm to 8:00 pm	8:00 pm to 11:00 pm (prime time)	11:00 pm to signoff
Network-aired spots:				
CDC-produced	80	0	16	132
Non-CDC-produced	119	0	58	253
Network total	199	0	74	385
Percent of total network airings by time of day	30	0	11	59
Local market-aired spots:				
CDC-produced	572	144	161	336
Non-CDC-produced	1,552	332	250	752
Local market total	2,124	476	411	1,088
Percent of total local market airings by time of day	52	12	10	26
Grand total	**2,323**	**476**	**485**	**1,473**
Percent of total airings shown during period	49	10	10	31

Appendix IV

Operation of the National AIDS Telephone Hotline

CDC contracted with the American Social Health Association to operate a national AIDS telephone hotline in September 1986. In September 1987, the association operated 17 telephone lines. Six were answered by a taped message giving the callers general AIDS information and directing them to an operator-assisted line if more information was desired, and 11 were operator-assisted. In anticipation of more inquiries resulting from the educational campaign, CDC modified the contract. This resulted in the establishment of 68 nationwide, toll-free lines operated from New York City and North Carolina. In October 1987, 24 taped message lines and 44 operator-assisted lines were operating.

One measure of telephone line adequacy is the busy-signal rate[1] when callers dial the hotline number. The contract, however, did not specify the maximum acceptable busy-signal rate until April 1988, when CDC amended it to require an average monthly busy-signal rate at or below 3 percent.

Data available from American Telephone and Telegraph Company for the New York City lines indicated that the busy-signal rates between October 1987 and March 1988 significantly exceeded the 3-percent standard established in April 1988 (see table IV.1). (Data were not available for the North Carolina lines.)

Table IV.1: Monthly Busy-Signal Rates for AIDS Hotline—New York City Area (October 1987-March 1988)

	Busy-signal rates (percent)	
Month	Taped	Operator
October	18	38
November	9	55
December	6	65
January	48	(Data unavailable)
February	21	33
March	18	28

According to CDC and past contractor project officers, because monitoring requirements were not included in the contract, CDC was unaware of these busy-signal rates until February 1988. CDC did not plan for the necessary monitoring requirements, CDC and contractor officials said, because CDC rushed the contract development to have the expanded hotline ready by October 1987.

[1]The busy-signal rate is computed by dividing the number of calls receiving a busy-signal during the month by the total number of calls attempted during the month.

Between July 28 and August 3, 1988, the system-wide busy-signal rate was 7 percent. The contractor said the busy-signal rates for calls to the North Carolina hotline increased from less than 1 percent to 50 percent for one hourly period following a public service announcement. The contractor is investigating technology to accommodate such periodic surges in demand as well as working with the networks to obtain advance notice of AIDS airings.

Appendix V

Distribution of the Pamphlet, What You Should Know About AIDS

HHS has printed 27 million copies of the pamphlet, What You Should Know About AIDS. Through large quantity orders (at least 6,000 copies) by organizations, such as state and local health departments, the GPO distributed 12.3 million of these copies between October and early December 1987. On September 30, 1987, CDC contracted with Aspen Systems Corporation to set up a National AIDS Information Clearinghouse, which distributed an additional 11.6 million copies as of July 15, 1988.

Aspen works with CDC's national AIDS telephone hotline in filling orders for AIDS informational materials. Requests for AIDS information received by the telephone hotline are recorded daily and sent to Aspen for order processing and mailing, according to a CDC official. CDC's contracts with Aspen and the hotline contractor require that telephone orders for AIDS information be delivered to the post office within 6 workdays of receipt of the telephone request.

To gain perspective on the time required to fill information requests through the telephone hotline-Aspen system, we requested copies of the What You Should Know About AIDS pamphlet 13 times between January 21 and February 18, 1988. In three cases, we did not receive the pamphlet. Of the 10 orders received, we were able to determine the mailing date for 7 orders. For these seven, it took an average of 12 workdays (ranging from 9 to 18 days) from request to delivery to the post office. Although our test was small, its results indicated that contract requirements were not being met consistently.

We informed CDC and Aspen officials of our preliminary findings. They stated that, through late February, the Clearinghouse was working to clear up a backlog of orders. The backlog was created, they added, by the unexpectedly large number of orders received and by delays in getting hotline requests to the Clearinghouse. As a result, in March we again placed telephone orders on 15 separate occasions and received all orders. It took 5 work days on average from request to delivery to the post office. Postal delivery required an average of 2 additional days.

Appendix VI

Status of Additional Projects to Educate the Public About AIDS

Several other federally sponsored events and activities intended to focus national attention on AIDS began in October 1987. The status of these CDC activities, which varied in scope and timing, follows.

Public Service Advertisements

Ogilvy & Mather (discussed in app. III) developed AIDS public service announcements for television and radio broadcast. Television announcements have been aired by both the networks and local stations, generally beginning in December 1987. Between October 1987 and February 1988, two radio networks (CBS Radio Network and RadioRadio) aired 199 announcements. The air time for these announcements was valued at about $1.2 million, as shown in table VI.1.

Table VI.1: CDC Radio Airings and Estimated Value (October 1987-February 1988)

Month	Number of airings	Estimated value
October 1987	59	$446,680
November 1987	50	286,460
December 1987	63	404,780
January 1988	14	43,200
February 1988	13	33,600
5-month totals	**199**	**$1,216,720**

Ogilvy & Mather also produced AIDS public service advertisements for magazine print. CDC approved these during the week of November 9, 1987. As of December 1987, we documented the publication of only two of these AIDS magazine advertisements.

Finally, the advertising agency also produced AIDS posters for display in public transit systems. Samples of the posters were sent to the Winston Network and the American Public Transit Association the week of January 25, 1988. The Winston Network sent samples to 25 of its clients in 15 cities in late February. According to an American Public Transit Association official, the Association did not distribute the sample materials to its membership until June 6, 1988.

Public Discussions, "Listening to the American Response"

During October 1987, CDC conducted 31 meetings in 28 cities to obtain public input regarding the AIDS issue. These meetings were attended by a total of about 400 people. The participants included AIDS service organization officials, such as hospice and local hotline staff, physicians and nurses, social workers, sex educators, teachers, and counselors.

Leadership Forums	Between September 1987 and January 1988, CDC conducted 12 forums to discuss AIDS and AIDS prevention in 7 major U.S. cities. A total of 408 people representing blacks, Hispanics, Asian-Pacific Islanders, disadvantaged women, youth, physicians, health care administrators, colleges and universities, community-based AIDS organizations, gay organizations, religious organizations, and journalists participated in these forums.
Business and Nonprofit Organization Partnership	On October 21, 1987, CDC published but did not distribute externally, according to CDC officials, a calendar of AIDS campaign activities. Included were activities initiated and sponsored by private sector entities, professional or service organizations, government entities, and CDC during the months August through November 1987. The calendar included a listing of 40 AIDS campaign activities scheduled by private sector organizations and 154 by the professional/service organizations during October 1987.
Information Sheets to Targeted Cities	In October 1987, Ogilvy & Mather sent requests to place AIDS information sheets on bulletin boards or magazine racks in 300 businesses located in Bloomington, Indiana, and Nashville and Memphis, Tennessee. About one-half of the businesses contacted were grocery stores, laundries, record stores, and barber/beauty shops. Thirty-three businesses agreed to post the information sheets. In mid-February 1988, English-language AIDS brochures were placed in about 6,600 supermarkets nationwide, according to a CDC official. CDC also planned to place Spanish language brochures in supermarkets serving predominately Hispanic population areas; as of July 1988, no brochures had been printed. The official attributed this primarily to difficulties in obtaining CDC clearance on the specific wording in the brochure.
Medical Professionals Information Seminar	On October 6, 1987, CDC and the American Medical Association jointly sponsored a 4-hour AIDS briefing for 33 medical, science and health reporters. CDC conducted no other informational seminars specifically for the medical profession, according to a CDC official.

Expert Spokespersons

In October 1987, CDC provided AIDS speakers for media speaking engagements on three occasions. Specifically,

- Dr. Gary Noble, Deputy Director of CDC for AIDS, was available for interview at an October 6 briefing for medical, science, and health reporters;
- Both U.S. Surgeon General C. Everett Koop and Dr. Walter Dowdle, Deputy Director of CDC, spoke at a 2-day conference entitled "AIDS: Corporate America Responds," attended by representatives from major corporations on October 13 and 14; and
- On October 20 and 21, Dr. Robert Windom, Assistant Secretary for Health, HHS, and Dr. Gary Noble were made available to 650 television stations for "face-to-face" satellite interviews. Dr. Windom was interviewed by seven stations and Dr. Noble by eight.

Appendix VII

Major Contributors to This Report

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Atlanta Regional Office	Don K. Riffe, Regional Management Representative Martin G. Landry, Evaluator-in-Charge Eva Z. Margolies, Site Senior Cynthia D. Forbes, Staff Member

The CHAIRMAN. I want to thank you very much, Dr. Noble.
Dr. NOBLE. Thank you, Mr. Chairman.
The CHAIRMAN. The committee stands in recess.
[Whereupon, at 12:45 p.m., the committee was adjourned.]

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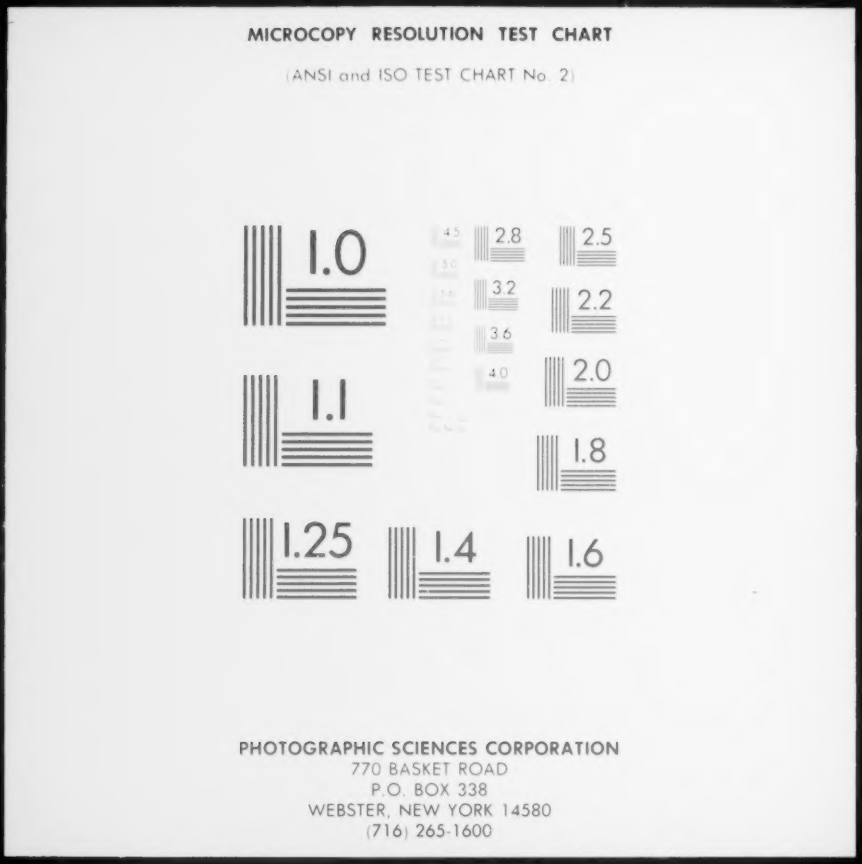

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